

COMPANION GUIDE · POST-MARKET SURVEILLANCE

THE SURVEILLANCE LOOP.

In The Clearance Gap, we named post-market surveillance as one of five problems boards discover rather than plan for. This is what the system underneath it actually looks like: the loop regulators expect you to run, in the EU and the US, and the one place in it that catches most manufacturers out.

General information, not regulatory or legal advice. Take advice specific to your device classification, your evidence strategy and your markets before you act.

A DEEPER LOOK AT PROBLEM THREE.

These are the issues we're seeing across today's MedTech market, the same five problems The Clearance Gap named:

- 1 Wrong regulatory pathway or classification.** Misjudged device classification, EU Medical Device Regulation Class I or IIa versus IIb or III, or US 510(k) versus De Novo versus Premarket Approval, derails timelines and investor confidence. The same misjudgement happens under the In Vitro Diagnostic Regulation, where getting the risk class, A, B, C or D, wrong carries the same cost for diagnostics makers.
- 2 Clinical evidence that satisfies the regulator but not the buyer.** Evidence built for clearance often doesn't fully support reimbursement or purchasing decisions.
- 3 Post-market surveillance treated as an afterthought.** The subject of this guide.
- 4 Software and AI-enabled devices facing overlapping regulation.** Unclear which obligation, medical device or AI-specific, bites first.
- 5 Market access misunderstood after clearance.** A CE mark, UKCA mark or FDA clearance isn't the same as a route to a sale, in the UK, the US or any other target market.

This guide goes deeper on problem three, since it's the one with the most moving parts underneath a single word. All five, and the arguments underneath them, are exactly what's up for debate over breakfast.

The five problems, the loops and the practice section are Andrew Dubowski's, Partner and Co-Founder, Clearpath HealthTech. The commentary, the diagram labels and the questions are AGENCY's.

WHY THIS EXISTS

THE PROBLEM ISN'T THE PAPERWORK, IT'S THE CONNECTION BETWEEN THE DOCUMENTS.

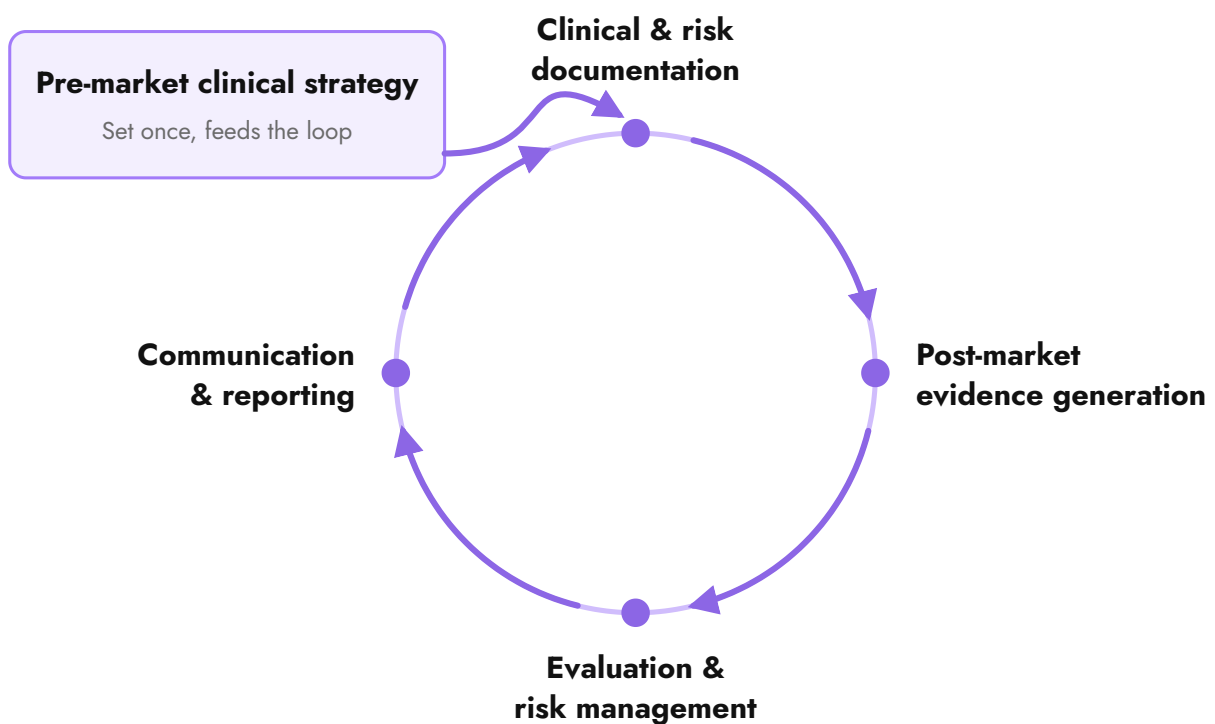
Post-market surveillance gets treated as five or six separate documents: a PMCF plan, complaints (that might lead to CAPA), vigilance, a PSUR, a CER update. It isn't. Under the Medical Device Regulation and under FDA's 510(k) framework, PMS is not simply a collection of reports. It's about collecting signals, evaluating safety and performance, and taking action where needed. The results of these actions must be fed back into both the product and the original documentation. A change in any part of the device, its packaging or its product information is designed to ripple through the rest.

Most manufacturers only discover how connected it is when a signal forces several departments to react to something none of them individually own.



THE EU LOOP.

Under the Medical Device Regulation, the pre-market clinical strategy is set once and leads to the preparation of the initial set of documents, then feeds a continuous loop: clinical and risk documentation updating, post-market evidence generation, evaluation and risk management, and communication and reporting, which updates the documentation and starts the loop again, for the life of the device and with fixed timelines for the whole process. The same loop applies under the In Vitro Diagnostic Regulation, with PMPF taking the place of PMCF.



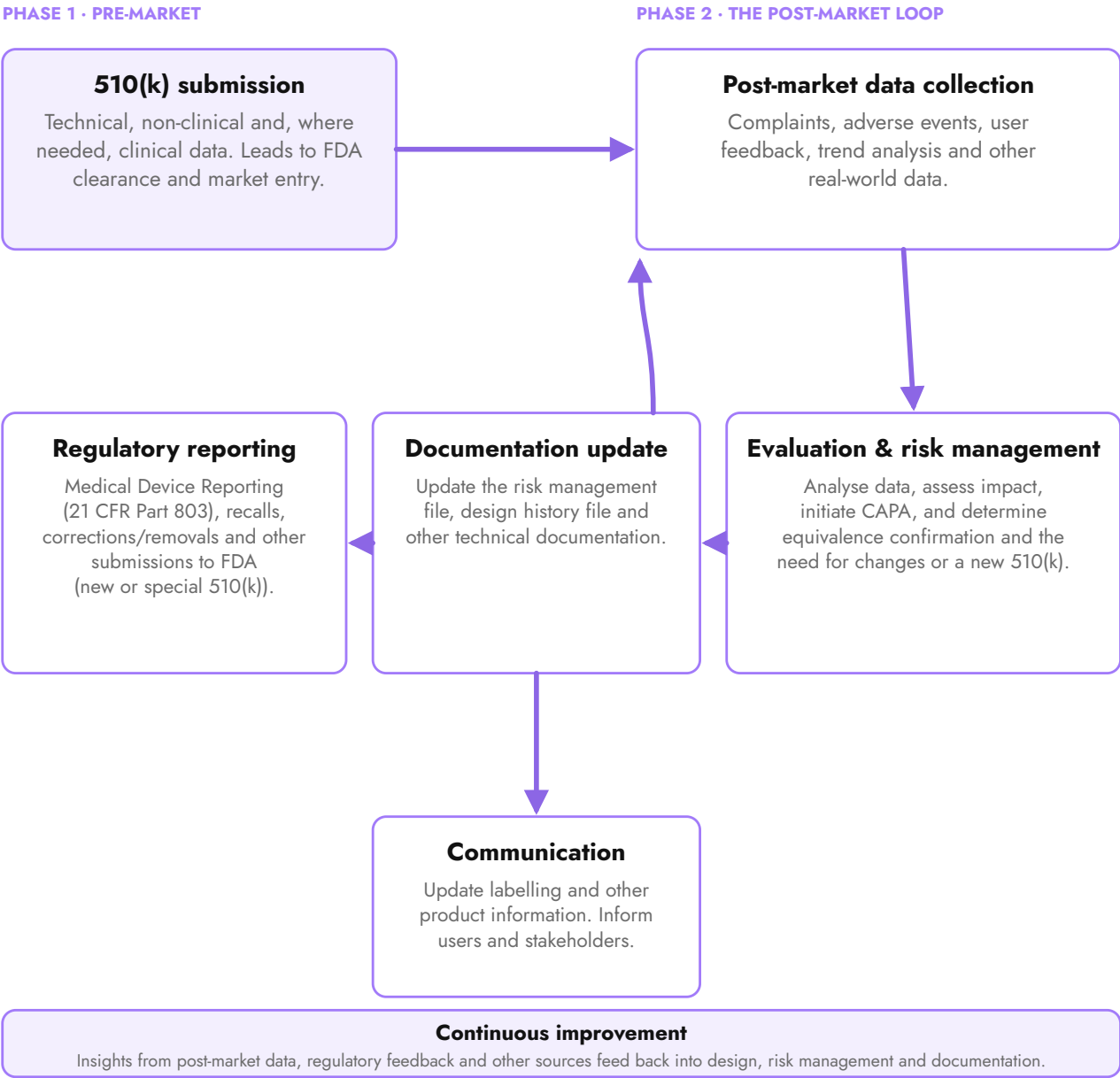
FOUR STAGES, ONE LOOP

Set once. The pre-market clinical strategy, which leads to the preparation of the initial set of documents, then feeds the loop.

- 1 Clinical and risk documentation updating.** Fed by the strategy first, then by every turn of the loop after it.
- 2 Post-market evidence generation.** What the device does once it is in real-world use, collected as data on the device's safety, performance and clinical experience.
- 3 Evaluation and risk management.** Evaluate the evidence for its impact on safety, performance and benefit-risk, and determine whether action is needed.
- 4 Communication and reporting.** Communicate relevant safety and performance information, update product information, and fulfil applicable regulatory reporting obligations.

THE US TWO-PHASE LOOP.

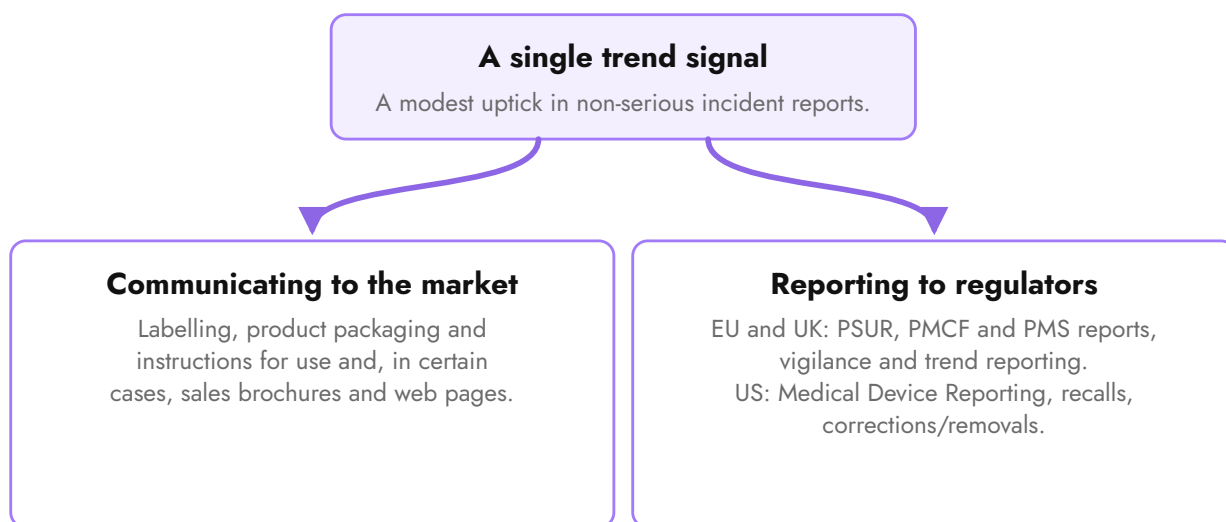
FDA's post-market obligations exist specifically to feed back into pre-market decisions. A signal detected after launch can force a design change and, if important enough, a new submission.



The 510(k) lifecycle for a Class II device, from pre-market submission to continuous monitoring and improvement, in accordance with the Federal Food, Drug, and Cosmetic Act and applicable FDA regulations.

WHAT WE SEE IN PRACTICE.

A single trend signal, something as small as a modest uptick in non-serious incident reports, can ripple through five or more separate pieces of documentation before most compliance functions even realise it's happening. Two flows get tangled here: communicating to the market (labelling, product packaging, instructions for use and, in certain cases, sales brochures and web pages) is not the same as reporting to regulators. According to the MDR, UKCA and FDA, a device's website might count as labelling too, which pulls digital marketing and social content into the same claims discipline as the printed material in the box. Regulatory reporting differs by market: PSUR/PMCF and PMS reports, vigilance and trend reporting in the EU/UK, and Medical Device Reporting, recalls and corrections/removals in the US. Manufacturers who treat them as one often update one and miss the other, or miss important regulatory deadlines.



The manufacturers who get ahead of this aren't the ones with the most paperwork. They're the ones who understand how the loop actually connects and keep both flows moving together, which is exactly what Clearpath's post-market surveillance platform is built to manage as one system, not five. They're also the ones who keep high quality products on the market, because they intervene in a timely manner.

The PMS system should not be designed after launch. It should be established as part of the QMS and PMS planning before market entry, considering that the regulatory architectures between MDR, IVDR and FDA differ quite a bit. Unfortunately, many manufacturers don't realise that.

The loop doesn't care which department owns which piece of paper.

JOIN US AT THE TABLE.

We unpack this loop, and the other four problems from The Clearance Gap, over breakfast with fellow MedTech leaders. Hosted jointly by AGENCY and Clearpath HealthTech at the Clifton Members Club, Bristol. This topic runs once eight people have registered interest, and there's no fixed date, so the sooner you register, the sooner it happens.



Register interest at agencymedicalmarketing.com/breakfast/medtech-regulation, or scan the code. The Clearance Gap, the guide this one accompanies, is free to read on the same page.

THREE QUESTIONS TO BRING TO THE TABLE

From problem three in The Clearance Gap. If you can answer all three on a Monday morning, your loop is running. If not, that is the conversation.

- Has anyone stress tested your vigilance system against next year's sales forecast, not against today's volume?
- Who owns post-market surveillance, and is it their whole job or a fraction of someone's?
- When did you last run a mock audit of your complaint handling and vigilance file, rather than wait for a real one?

This guide is AGENCY and Clearpath HealthTech's own reading of the position as at September 2026, written as marketers and regulatory specialists, not as lawyers. General information, not regulatory or legal advice. Take advice specific to your device classification, your evidence strategy and your markets before you act. Rules change and vary by country; check the current position before acting on anything here.

Written with Andrew Dubowski, Partner and Co-Founder, Clearpath HealthTech. AGENCY hosts the breakfast series. Full attribution is on page 01.



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