AGENCY
HEALTHCARE DEMAND GENERATION

Clearpath Healthtech

FREE GUIDE · NEW MARKET ENTRY

THE CLEARANCE GAP.

Clearance lets you sell. It doesn't make anyone buy. Most of the regulatory and clinical problems MedTech owners face trace back to that gap, and it is why market entry timescales are so unpredictable at board level. The five problems Clearpath sees most often, how to spot each one in your own business, and what good looks like.

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

WHY THIS GUIDE EXISTS

AIM, PROBLEM, VISION, MISSION.

AIM

To show you why market entry timescales are so unpredictable at board level: the five regulatory and clinical problems Clearpath sees most often in MedTech owners, why each one happens, how to spot it in your own business on a Monday morning, and what good looks like.

PROBLEM

Clearance and commercial adoption get treated as the same milestone. They are not. Most MedTech owners discover the regulatory pathway was the easier half: the evidence a regulator accepts is rarely the evidence a payer or the National Health Service acts on, and a CE marking or UK Conformity Assessed mark gets mistaken for market access rather than permission to attempt it.

VISION

A market entry plan that treats regulatory strategy, clinical evidence, post-market surveillance and National Health Service access as one sequence, agreed in order, rather than four departments discovering each other's decisions after the money has been spent.

MISSION

Make the gap between clearance and commercial adoption visible before it costs a funding round or a launch date.

The five problems are Andrew Dubowski's. The commentary and the questions are AGENCY's.

THE THESIS

CLEARANCE IS NOT THE FINISH LINE.

Boards treat a regulatory mark as a milestone with a date attached, because it is the one part of market entry with a defined process and a defined reviewer. Everything after it, evidence that convinces a payer, a vigilance system sized for scale, procurement inside a health system that runs on frameworks and committees, has no equivalent milestone, so it does not get a date. It gets discovered.

That is why market entry timescales are so unpredictable at board level. Not because regulatory teams are slow, and not because the science is uncertain. Because the plan only ever modelled the part that has a form to fill in, and the five problems in this guide are the parts that do not.

Each one on its own looks like a specialist's problem: a classification question for regulatory affairs, a health economics gap for market access, a vigilance resourcing question for quality. Together they are the same problem wearing five different departments' clothing: clearance was never the same thing as commercial adoption, and nobody built a plan that treated it that way.

PROBLEM 1 OF 5

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.

WHY IT HAPPENS

Classification usually gets decided early, by whoever is in the room before the regulatory strategy has been pressure tested, and it is decided around the pathway the company wants rather than the one the device's intended purpose and risk profile actually require. A borderline device, software-adjacent, a combination product, a genuinely novel mechanism, has no clean precedent to anchor the decision, so the assumption made at the start survives by default rather than by argument. Nobody revisits it as the claims or the intended use shift during development, until a notified body or a reviewer disagrees.

SPOT IT IN YOUR BUSINESS

- Can you point to the specific clause in the classification rules, not a slide, that justifies your device's class?
- Has the classification been reassessed since the last real change to intended use, claims or software function?
- If a notified body or the FDA disagreed with your classification tomorrow, do you know the fallback pathway and what it would cost you in time?

WHAT GOOD LOOKS LIKE

A classification written down with the specific rule cited, agreed before development spend accelerates, and reopened every time the intended use or the claims change. The board sees a route and a realistic timeline instead of a date carried over from the original business plan.

The fastest pathway and the right pathway are only the same one by accident.

PROBLEM 2 OF 5

CLINICAL EVIDENCE THAT SATISFIES THE REGULATOR BUT NOT THE BUYER

Evidence generated for clearance does not support reimbursement or purchasing decisions.

WHY IT HAPPENS

Regulatory and health economics evidence get built by different teams, on different timelines, answering different questions. A safety and performance file satisfies the regulator's threshold, which is a question about risk and intended purpose. A payer or an NHS budget holder asks a different question entirely: what does this replace, and does it save enough or improve outcomes enough to justify the price. Companies plan the clinical study first and ask the health economics question only once the data is locked, by which point the study cannot be redesigned to answer it.

SPOT IT IN YOUR BUSINESS

- Did anyone from procurement, health economics or your NHS-facing commercial team see the study design before it started, or only the results after?
- Can your current evidence answer what a budget holder will actually ask: what does this replace, and what does it save?
- If NICE asked for your health economic model tomorrow, do you have the inputs, or would you be starting from the clinical file alone?

WHAT GOOD LOOKS LIKE

The evidence and health economics strategy is designed backwards from the reimbursement or NHS decision the product needs to win, not forwards from what the regulator will accept. The regulatory and health economic conversations happen in the same room, early, not in sequence months apart.

Evidence that only satisfies the regulator has done half the job it needed to do.

PROBLEM 3 OF 5

POST-MARKET SURVEILLANCE TREATED AS AN AFTERTHOUGHT

Vigilance obligations under-resourced, creating exposure at audit or on market expansion.

WHY IT HAPPENS

Post-market surveillance gets budgeted and staffed as a compliance cost during the pre-launch scramble, when every pound is going towards getting the device cleared and to market. It is built to the minimum the regulation requires, for one market, on day one, and nobody revisits the resourcing as the device sells into new territories or as complaint volumes rise with sales volume. A system that was adequate for a fifty unit pilot is not adequate for a five thousand unit rollout, and the gap is invisible until an auditor, or a new market's regulator, asks to see it.

SPOT IT IN YOUR BUSINESS

- 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?

WHAT GOOD LOOKS LIKE

A post-market surveillance system sized for where the business is going, not where it started, reviewed on a schedule rather than in response to a crisis, with clear ownership and a complaint to corrective action loop that would survive an unannounced audit.

The vigilance system that passed on day one is not the one your auditor will ask to see on day one thousand.

PROBLEM 4 OF 5

SOFTWARE AND AI-ENABLED DEVICES FACING OVERLAPPING REGULATION

Software as a Medical Device and artificial intelligence-enabled devices now sit under both medical device regulation and emerging artificial intelligence-specific rules, the EU Artificial Intelligence Act, and it is unclear which obligation bites first.

WHY IT HAPPENS

Two regulatory regimes were built by different institutions, on different timelines, for different reasons: medical device regulation for patient safety, the EU Artificial Intelligence Act for algorithmic risk and transparency. But the two are meant to be assessed together. The Artificial Intelligence Act allows one combined conformity assessment and lets you extend the technical file you already hold. What is usually missing is anyone sequencing the two workstreams, so they run in parallel and some of the work gets redone.

That timing pressure has moved, not disappeared. The AI Omnibus, proposed by the European Commission and in force across the EU since 27 July 2026, extended the timelines without removing the obligations. High-risk requirements for AI systems embedded in products regulated elsewhere, which is where AI-enabled medical devices sit under the Act's Annex I, now apply from 2 August 2028 rather than 2027. Standalone high-risk systems under Annex III move to 2 December 2027. Treat 2028 as a longer sequencing window, not a reprieve, and the redone work above never has to happen at all.

SPOT IT IN YOUR BUSINESS

- Does one team own both your medical device conformity work and your Artificial Intelligence Act obligations, or do they sit in separate reporting lines that only meet at the end?
- If your risk classification changed under either framework tomorrow, would you know what it changed for the other?
- Have you mapped which conformity assessment happens first, and what it locks in for the second?

WHAT GOOD LOOKS LIKE

One conformity roadmap, built now while 2028 still gives you room to sequence it properly, that lets the evidence and documentation built for one framework be reused, not duplicated, by the other.

A later deadline is not a shorter to-do list.

PROBLEM 5 OF 5

NATIONAL HEALTH SERVICE PROCUREMENT MISUNDERSTOOD AFTER CLEARANCE

A CE marking or UK Conformity Assessed mark is mistaken for market access. Owners don't know the real National Health Service buying journey.

WHY IT HAPPENS

The regulatory mark is a hard-won, visible milestone, so it is natural to treat it as the finish line. It only confirms the device is legal to sell. It says nothing about which framework agreement it needs to sit on, which budget holder controls the spend, or which trust or integrated care board actually decides. Companies that have never sold into the NHS assume a sale works the way it does in a private market, find the willing buyer, agree a price, and are caught out by a procurement system built around frameworks, tenders and committees they did not know existed.

SPOT IT IN YOUR BUSINESS

- Could you name the framework agreement your product needs to sit on to be purchased by an NHS trust?
- Do you know who the actual budget holder is for your product category, and is it the person your sales conversations have been happening with?
- Has anyone mapped the realistic route and timeline to a first NHS sale, or is your launch plan assuming private market speed?

> **WHAT GOOD LOOKS LIKE**
>
> A market access map that names the framework agreements, the budget holders and the realistic route and timeline to a first sale, built before the regulatory mark lands, so commercial activity starts the day clearance does rather than months after it.

A CE mark tells you the door is unlocked. It does not tell you which corridor to walk down.

HOW CLEARPATH RESOLVES THESE

FIVE PROBLEMS. ONE SEQUENCE.

Collected here, once, so the guide above stays a guide and not a pitch interrupted five times.

01 WRONG REGULATORY PATHWAY OR CLASSIFICATION

A pathway diagnostic that gives a defensible route and a realistic timeline before you spend on the wrong strategy.

02 CLINICAL EVIDENCE THAT SATISFIES THE REGULATOR BUT NOT THE BUYER

An evidence and health economics strategy, designed backwards from the payer or the National Health Service decision, not just the submission.

03 POST-MARKET SURVEILLANCE TREATED AS AN AFTERTHOUGHT

Right-sized post-market surveillance system design and remediation, delivered through Clearpath's own ClearVision platform.

04 SOFTWARE AND AI-ENABLED DEVICES FACING OVERLAPPING REGULATION

A conformity roadmap through Clearpath's dedicated artificial intelligence governance service line, sequencing both frameworks without duplicated effort.

05 NATIONAL HEALTH SERVICE PROCUREMENT MISUNDERSTOOD AFTER CLEARANCE

A National Health Service market access diagnostic mapping framework agreements, budget holders and the realistic route to a sale.

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. The EU Artificial Intelligence Act (the AI Act) timelines referenced above reflect the AI Omnibus, in force since 27 July 2026, sourced to the European Commission's own published timeline (https://digital-strategy.ec.europa.eu/en/news/ai-omnibus-enters-force), and may be revised again. This is general information, not regulatory or legal advice, and not a substitute for advice on your device, your evidence and your markets. Rules change and vary by country. Take your own advice, and check the current position, before acting on anything here.

Hosted jointly by AGENCY and Clearpath HealthTech. Andrew Dubowski, Partner and Co-Founder, Clearpath HealthTech. This guide doubles as the agenda. We run it at the Clifton Members Club in Bristol, and a topic runs once eight people have registered interest, so there is no fixed date.

AGENCY
HEALTHCARE DEMAND GENERATION

Michael Colling-Tuck
mct@agencybristol.com
agencymedicalmarketing.com

Clearpath Healthtech

Andrew Dubowski
andrew.dubowski@clearpathhealthtech.com
clearpathhealthtech.com