AI in MedTech is moving from promise to proof

Medtech and diagnostics innovators are under growing pressure to do more with less. They must generate stronger evidence, move faster, and navigate evolving regulation, all while managing increasingly complex data.

At CPI's Innovation in MedTech and Diagnostics Conference in October 2025, a clear message from keynote speaker Chris McCurdy, formerly the CTO Healthcare & Life Sciences at Amazon Web Services (AWS) stood out: the teams that get their data strategy right, and apply AI where it delivers real value, will shape patient outcomes over the next decade.

Six months on, that message has become more urgent.

As CPI prepares for this year's Innovation in MedTech and Diagnostics Conference on 6–7 October 2026, AI is not just part of the agenda, it is shaping it. Sessions already point to where the sector is heading, including AI-powered molecular pathology and multimodal data in neurology.

The potential is significant, but the expectations are rising just as quickly. Across MedTech and diagnostics, the conversation around AI has shifted. There is less focus on pilots and experimentation, and more focus on deployment, evidence generation, and integration into real clinical and regulatory pathways.

This reflects what CPI is seeing across translational R&D and scale-up programmes. Success is no longer defined by whether AI can be built, but whether it can be trusted, validated, and adopted.

What's changed in 2026

1. From pilots to proof

In 2025, many organisations were still exploring AI through pilots and internal demonstrations. In 2026, that is no longer enough:

- Solutions must generate clinically and commercially relevant evidence.
- Outputs must stand up to regulatory scrutiny.
- AI must integrate into existing clinical and operational workflows.

This shift is happening in a more active innovation environment. In the UK, approved clinical investigations for medical devices increased by 17% in 2025, reflecting growing momentum in translating innovation into regulated, real-world use.

At the same time, regulatory expectations are becoming more defined. The EU AI Act begins to apply from August 2026, with further obligations for high-risk AI systems, including those embedded in medical devices, following in 2027. For medtech teams, this raises the bar on evidence, traceability, and compliance from the outset.

2. Data readiness is now a competitive advantage

The gap between organisations with strong data foundations and those without is widening. Teams that treat data as a product are moving faster into validation and generating stronger, more defensible evidence. Critically, they're also able to progress more smoothly through

regulatory pathways. Those without this foundation remain constrained by fragmented, unstructured, and poorly governed data.

Industry data reflects this shift with around 53% of MedTech executives now see investment in AI-enabled platforms as a key growth driver, while 82% identify AI-enhanced workflows and health IT as immediate revenue opportunities. AI capability is becoming a differentiator, but only for organisations with the data foundations to support it.

Chris McCurdy summed it up powerfully: "AI isn't the magic, your data is. If you can't find it, trust it, or share it, AI won't fix that. Start with good data, and the rest will follow." His advice for SMEs was to start small. Identify one or two valuable datasets, perhaps verification studies or assay results, define owners, and add basic metadata (purpose, limitations, quality metrics). That discipline lays the groundwork for meaningful AI adoption.

3. Agentic AI is moving closer to real use

Agentic AI is rapidly evolving from a conceptual framework into early-stage application within diagnostics and laboratory environments. In Chris's presentation, he highlighted emerging use cases in life sciences, including how AWS has demonstrated the potential of these systems to automate biomarker discovery. By autonomously accessing complex datasets, performing statistical analyses, and generating visual outputs, agentic AI can significantly reduce reliance on manual intervention, which accelerates both insight generation and decision-making.

With agentic AI, the most immediate opportunities are not fully autonomous systems, but structured, high-value workflows, such as:

- Supporting assay data interpretation.
- Automating documentation and reporting processes.
- Bringing together data from multiple sources to support faster decisions.

These use cases align closely with the direction of this year's conference, where AI is positioned as part of the next generation of diagnostic capability, rather than a standalone innovation. However, the same constraint remains, without structured, well-governed data, these approaches do not scale or meet regulatory expectations.

4. Regulation and trust are now central

AI in diagnostics is no longer just a technical challenge. It is a regulatory and adoption challenge.

Regulators are actively evolving their approach with the FDA has signalling that it will continue updating its list of AI-enabled medical devices, including improving how systems using large language models and foundation models are identified and assessed.

Across regions, there is increasing focus on:

- Traceability of data and models.
- Transparency of outputs.
- Reproducibility of results.
- Alignment with clinical decision-making.

5. The opportunity for MedTech SMEs

For MedTech SMEs, this shift creates a clear opportunity, but also a need for focus. It's no longer necessary to build large-scale AI platforms to create value, success can come from:

- Targeting specific, high-value clinical or operational decisions.
- Ensuring supporting data is usable, structured, and trusted.
- Generating evidence that supports adoption and regulatory approval.

This focused, entrepreneurial approach is more aligned with how the market is evolving and will be critical for SMEs looking to translate innovation into impact.

From experimentation to impact

AI in MedTech and diagnostics is still difficult to implement effectively and the organisations making meaningful progress are not necessarily those with the most advanced models. They are the ones that can connect:

- Data readiness.
- Governance and compliance.
- Evidence generation.
- Real-world workflow integration.

As the sector comes together at CPI's Innovation in MedTech and Diagnostics Conference on **6–7 October 2026**, AI will be a central theme, not just because of its potential, but because of the challenge of making it work in practice.

Book your place at this year's conference: www.uk-cpi.com/events/healthtech-conference-london-2026