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Shaping society 5.0 Building trust in AI as a force for good

Shaping trust in AI: How regulation
can help us unlock the true power
of AI



Foreword



**By Harold Pradal,
Chief Commercial Officer, BSI**

2023 will be viewed as the point that Artificial Intelligence (AI) tipped into the mainstream, with a 286% rise in media coverage of the topic¹. And whilst headlines were grabbed by ChatGPT, the real AI story is much, much deeper.

This transformational technology is accelerating progress – and has the potential to go further as a force for good and move us towards Society 5.0, a ‘human-centered society that balances economic and technological advancement to solve society’s problems’². Importantly, it also raises questions around how we build trust in AI and what guardrails are needed to ensure AI shapes our future in a positive way.

In this collection we go behind the headlines to explore the real-world impact of AI through the eyes of BSI experts, drawing on the views of 10,000 people in nine countries. For anyone in doubt, AI is here and it’s here to stay – 38% of people use AI in their jobs daily, rising to 70% in China and 64% in India. By 2030, 62% expect their industry will use AI³.

At BSI we are committed to shaping the impact of technology and innovation for the benefit of individuals, organizations and society. AI sits at the heart of this because it has the potential to be a powerful partner, changing lives and accelerating progress towards a better future and a sustainable world.

We commissioned these essays to turn the spotlight on this generational opportunity – recognizing that the better we understand it, the better we can harness its power. Whether it’s creating new workplace opportunities, improving patient outcomes, tackling modern slavery or building a safe global food system, AI has a pivotal role to play.

We examine the importance of embedding digital trust in AI, the critical role for collaboration – between nations, policymakers, organizations and individuals – to unlock AI’s true potential, and the fast-evolving regulation designed to ensure consistency and certainty.

With AI crossing over from small, contained environments into mainstream technology at work and at home, this offers a transformational opportunity to unlock a multitude of benefits – provided trust and confidence are present too.

AI is just getting started. At BSI we are excited to partner with our clients as we embark on this journey. We are delighted to present these essays to explore the enormous potential AI offers to shape Society 5.0 and deliver a sustainable future powered by innovation.

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Shaping trust in AI: How regulation can help us unlock the true power of AI

As a purpose-driven organization, BSI believes AI can be a force for good, changing lives, making a positive impact to help create a better society and accelerating progress towards a sustainable world. In this essay, Mark Thirlwell looks at the medical devices sector and how building trust, including through regulation, can ensure AI can be a force for good for patients.





By Mark Thirlwell

Managing Director, AI Regulatory Services, BSI

From cars to commercial aircraft, safety measures are an integral part to ensuring that anything moving at great speed reaches its desired destination. And there's no doubt that AI is travelling with great speed and has the potential to act as a force for good across every aspect of society, from healthcare to home and from commerce to climate change.

However, the huge benefits to society that AI offers must be underpinned by trust – whether that is in AI-powered medical devices or the biometrics that could one day make cross-border travel a seamless experience. There are many different ways we can develop this trust, from guardrails put in place by developers and organizations to consensus-led standards and certification around governance, and, of course, international regulation.

When it comes to the medical devices sector, the EU Artificial Intelligence Act, the world's first comprehensive AI law, is a real breakthrough moment – offering a route for doctors and healthcare practitioners to partner safely and securely with technology to improve the patient experience and ultimately save lives.

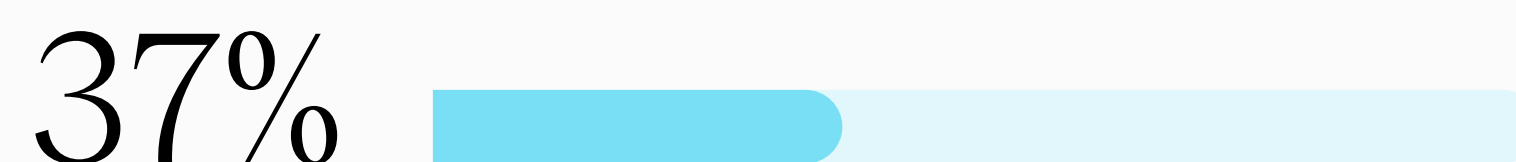
- AI has the power to transform many areas of our lives – not least to improve the patient experience and ultimately save lives.
- Regulation in key areas can ensure AI delivers as a force for good with consistency and certainty.
- The EU's AI Act represents a stake in the ground to encourage nations to come together and embrace a consistent global approach.

The AI revolution in medical devices

It's worth exploring the medical device sector in more detail because this is arguably the field where AI is making the biggest impact thus far. This year alone the AI medical devices sector is expected to grow to \$15.42 billion, a compound annual growth rate of 45%. And as BSI's Trust in AI Poll⁴ found, 29% of people in healthcare report currently using AI in their job on a daily basis, while a further 57% working expect their sector to do so by 2030. On the patient side, 37% of people said they expect to see AI used when they are at the doctors or a hospital (for example, cameras to detect illnesses) by 2030.

What we're seeing today is many manufacturers starting to embrace AI in medical devices⁵, from surgical robotics – where AI can assist surgeons in conducting some of the most delicate operations⁶ – to diagnostics including disease detection, identifying heart issues⁷ or picking up foetal anomalies in early pregnancy⁸. There are some remarkable outcomes already being achieved, for example with AI tools to detect breast cancer even before symptoms appear⁹.

These are timely and welcome developments that can help ensure that AI is a force for good, for today and the future.



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Trust is the lynchpin

BSI's research revealed that 52% of people are excited about the potential for AI to improve the accuracy of a diagnosis or speed up recovery times. 56% support the use of AI tools to diagnose or treat them or a loved one if it can improve their condition or speed up recovery, and 55% support the use of AI tools to diagnose or treat them or a loved one if there are strict safeguards to ensure ethical use of patient data in place.

At its very best, this is transformational technology, but understandably the public wants reassurance. 57% said the tools should be overseen by a qualified person. And three quarters (74%) say they need a strong level of trust when AI is used for medical diagnosis or treatment (for example, analysing X-ray images and creating personalized treatment plan based on the patient's age and lifestyle).

We have this fantastic opportunity to transform medical treatment and make people not just healthier but able to live better lives while they are being treated. And in some countries the enthusiasm for this is there – it was striking that 80% of people in India and 72% of people in China said they were excited about AI's potential to improve diagnosis or recovery times – but there is journey to build this excitement elsewhere. In France, the Netherlands and Germany less than half felt this way, with just 43% in the latter expressing this optimism.

It's completely reasonable – after all we are talking about people's lives. But given the potential gains, if we don't take steps to build trust in the use of AI in the medical devices space, the risk is that we will lose out on the enormous potential this technology offers.

As IBM's interviews with AI scientists make clear¹⁰, we can ensure people recognize the potential benefits by taking steps to guarantee that AI does exactly what it says it's going to do and nothing else. This means ensuring that it's trustworthy, ethical and potential bias is addressed. It means a human participates in the overall process and that the output of the AI is explainable.

As we seek to expand our AI horizons, in medical devices and beyond, it's critical that we complement innovation and progress with safe and ethical deployment. This is where regulation could play a crucial role.



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Mark Thirwell



The impact of the EU AI Act

Our survey found that 40% of people use AI in their jobs every day and that people are using AI across every sector. With different industries considering questions such as how AI can be used to drive the performance and safety of products, regulation, alongside compliance with high industry standards, is likely to play an increasingly pivotal role in the development and deployment of this emerging technology.

The EU AI Act, due to be finalized imminently with a two- or three-year roll-out period, represents a step forward for legislation in this field – it is designed to be clear, prescriptive and flexible. Amongst its provisions¹¹, the AI Act will establish obligations for providers and users depending on the level of risk posed by the AI, while also requiring generative AI tools like ChatGPT to comply with transparency rules.

From there, there is an opportunity for other nations around the globe to also embrace this approach, in the same way that GDPR¹² has set the baseline for data regulation since its introduction five years ago. Today, many non-European countries have similar regulation in place¹³, including Japan¹⁴, South Korea¹⁵ and South Africa¹⁶.

This kind of oversight is intended not to stifle innovation, but to encourage it by delivering clarity and confidence in AI development – something that can be good news for investors and consumers who need to trust new products and services as they emerge. Offering clarity and instilling confidence in the development, products, and services of AI has the potential to increase the public's willingness to adopt the technology quickly, accordingly, driving demand and encouraging innovation around AI-enabled technology.

Given the timeframes, organizations seeking to put AI at the heart of their operations can be on the front foot by planning for the regulation so that they can proceed with confidence. And they can approach this not as red tape to comply with but a crucial safeguard to ensure that the AI being deployed is ethical, fair and transparent.





The medical angle

One of the great strengths of the AI Act is that it is horizontal legislation, which runs across different sectors. For example, where there's already legislation in place for medical devices, the AI Act will be bolted on to that and ensure that all elements of the medical device are safely regulated. Any organization wishing to take its medical device to market in Europe will need to conform to the AI Act by the end of the transition period, which is likely to be in 2026 or 2027. Although that will require new processes, having this in place could help boost the excitement of people in Europe about the potential gains to be realized from AI in medical care.

At BSI we have a strong track record in the safe adoption of medical devices, proven history in bringing together specialization to develop AI standards, including new AI guidance designed to build trust for patients whether they are receiving care in hospital or at home, and one of the largest medical device-notified bodies in Europe. The AI Act can work well with current Medical Devices Regulations¹⁷ (MDR) to ensure that across society people can benefit from these technologies safe in the knowledge that they can trust them.

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Time for a global approach

Whilst the AI Act is a significant stake in the ground, global agreement is the next step. As noted above, there's the potential for the AI Act to set the standard in much the same way as GDPR¹⁸ has. At the same time it's important to acknowledge that, with AI, the EU is taking a different approach to the US, China and even the UK¹⁹ – although it is early days. Uniting divergent perspectives on this fundamental topic will require great effort and collaboration but ultimately ensuring consistency, both for the management of risk and for certainty within the industry, could offer the greatest benefits.

Time will tell as to how the world responds to AI. Given the amount of innovation we are seeing in the medical devices sector, the potential for AI to change for the better how we diagnose, treat and care for people experiencing medical conditions is evident. Embedding trust is absolutely pivotal. Whether we do so through global regulation or other steps, or both, if we want to unlock the true power of AI, the sooner this happens, the sooner we can reap the benefits.

Find out more

BSI is currently working towards designation as an AI notified body to deliver product certifications. The AI notified body will focus on certification of high-risk AI products that require notified body oversight. [Read more about our developments here.](#)

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