

Key considerations and questions for suppliers and your organisation

Key consideration	Questions to ask suppliers	Organisational considerations
What level of regulatory approval has been undertaken and what evidence exists on clinical safety?	<ul style="list-style-type: none">• Is the product regulated as a medical device?• What level of regulatory approval does a product have?• Does the product have UKCA or CE accreditation?• What use does the AI have regulatory approval and certifications for? Are there any exclusions or limitations to be aware of?• What evidence is there supporting the safety and effectiveness of the AI? Does evidence exist in real-world settings?	<ul style="list-style-type: none">• Have regulatory frameworks changed and if so, do they impact your adoption of a new product?• Do you have access to evidence on documented impact and safety assessments?• How will post-market surveillance be managed?• Are incident reporting processes in place?
What governance and board assurance processes do you have in place?	<ul style="list-style-type: none">• What is the AI solution designed to do and who is it designed for?	<ul style="list-style-type: none">• Does the intended use of the AI solve issues you are currently facing?• Do you have internal governance processes and structures in place? How do they feed into board decision making?• Do you have existing policies on AI, Information governance and security, data protection and ethics? Do these need updating?• How will the effectiveness and safety of an AI tool be monitored once it has been adopted?

Key consideration

Questions to ask suppliers

Organisational considerations

How can you demonstrate cost-effectiveness and return on investment (ROI) of AI tools?

- What evidence does the supplier hold on the cost-effectiveness of the AI tool?

- Does the intended use of the AI solve issues you are currently facing?
- Does the tool align to organisation strategy and procurement standards and is it a logical next step?
- What skills, capabilities and infrastructure are needed that are not already in place? How will these be funded?
- How confident are you in the reliability of datasets?
- What data is needed to prove ROI?
- How will you demonstrate Return on investment for the AI tool?
- Are there learnings from pilot projects that can inform business case development for new AI tools?
- How do the results compare to the effectiveness without the use of AI? Is the AI adding value?

Can AI tools be integrated within clinical pathways and workflows?

- What support is available from the supplier to integrate tools into existing systems and pathways?

- How will AI tools be integrated into existing clinical workflows?
- What level of effort will be required to integrate the solution into existing pathways and processes?
- Taking into account the differences between organisations and the populations they serve, are there any learnings on roll-out and implementation that can be shared between organisations?

Continues...

Key consideration

Questions to ask suppliers

Organisational considerations

Is the data and digital infrastructure in place?

- Will changes be required in IT and digital systems and data management?
- Have you assessed your level of data readiness and interoperability to support AI rollout?
- Which cybersecurity measures need to be in place?
- Has a data protection impact assessment (DPIA) been completed?
- What implementation support within your infrastructure is required?

How will the workforce be supported and trained on new tools?

- What training support is available from the supplier?
- What implementation support is provided by the supplier?
- Which staff will have access to AI tools?
- What skills and capabilities are needed to support the adoption of new tools?
- What training opportunities will be open to staff?
- What information will be shared with staff on the use of AI tools and the organisational position?
- How can information on the benefits of AI tools and learnings from any pilots be shared amongst staff?
- How will any training initiatives align with wider organisational work on digital maturity?
- Are there sufficient 'human in the loop' opportunities and are staff clear on the level of checking of AI tools required?
- How will you ensure that workforce planning reflects the evolving and changing roles of staff impacted by AI?

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<p>How is lived and living experience being factored into development and testing of new tools? What steps will be taken to build patient understanding and compliance?</p>		<ul style="list-style-type: none"> • How do you involve people with lived and living experience in the development of AI tools? • What processes do you have in place to gather patient and carer feedback and insights on AI tools? • Is the lived and living experience voice represented in any of your AI or digital groups? • What mechanisms are in place to ensure clear and transparent communication and the provision of information for patients and service users, about AI?
<p>How can we ensure AI is ethical and doesn't increase health inequalities?</p>	<ul style="list-style-type: none"> • Does the supplier uphold industry environmental standards? 	<ul style="list-style-type: none"> • How will post-market surveillance be managed? • How can you ensure that real world evidence is reviewed to consider any impact on health inequalities? • How are equity and ethical considerations factored in from the start and monitored throughout, so consideration can be given to which groups of the health population will benefit and how any widening health inequalities can be mitigated • How are biases being identified when considering a proof of concept AI project? • How are you considering the environmental impact of the AI tool and taking steps to mitigate this if implemented?