



Commercialization of medical artificial intelligence technologies: challenges and opportunities

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Artificial intelligence (AI) is already having a significant impact on healthcare. For example, AI-guided imaging can improve the diagnosis/treatment of vascular diseases, which affect over 200 million people globally. Recently, Chiu and colleagues (2024) developed an AI algorithm that supports nurses with no ultrasound training in diagnosing abdominal aortic aneurysms (AAA) with similar accuracy as ultrasound-trained physicians. This technology can therefore improve AAA screening; however, achieving clinical impact with new AI technologies requires careful consideration of commercialization strategies, including funding, compliance with safety and regulatory frameworks, health technology assessment, regulatory approval, reimbursement, and clinical guideline integration.

Artificial intelligence (AI) technologies are already having significant impacts in healthcare¹. For example, AI-guided imaging has shown promise in the management of vascular diseases, including carotid, aortic, and peripheral artery disease, which collectively affect over 200 million individuals globally and lead to significant mortality/morbidity related to catastrophic complications such as aneurysm rupture, stroke, and limb loss^{2–4}. These diseases are typically managed by vascular specialists who rely on imaging modalities including ultrasound, computed tomography (CT), and fluoroscopy for diagnosis/treatment⁵. Recent advancements, such as three-dimensional reconstruction software and fluoroscopic roadmaps, have transformed pre-operative planning and intra-operative guidance⁵. However, despite the growing availability of AI tools, their integration into routine diagnostic vascular imaging remains limited. This is largely due to persistent financial, regulatory, and implementation challenges that impede clinical translation. Many AI solutions are developed without adequate alignment to regulatory pathways or quality assurance frameworks, which hinders their adoption in practice⁶. This is particularly concerning given that vascular diseases are frequently underdiagnosed⁷. For example, abdominal aortic aneurysms (AAA) are often captured incidentally on medical images obtained during the investigation of other abdominal concerns, including assessment of liver, gallbladder, and kidney conditions, rather than actively screened for despite guideline recommendations⁸. Consequently, many

AAA's remain undetected until rupture, which carry mortality rates up to 80%⁹. AI-enhanced imaging holds potential to increase screening uptake and facilitate timely, elective intervention prior to rupture¹⁰. In this article, we examine a recently developed deep learning algorithm for AAA screening and explore the broader challenges and opportunities associated with commercializing AI technologies to deliver tangible clinical impact.

From algorithm to impact: a validated AI tool for aneurysm screening

Ultrasound screening for AAA is systemically underperformed primarily due to the global shortages of trained ultrasound technicians and imaging specialists, particularly in low-resource settings^{11,12}. Chiu and colleagues (2024) recently developed and prospectively validated an AI tool that supports nurses with no ultrasound training in diagnosing AAA with 100% sensitivity and 97.8% specificity¹³. The study enrolled 184 patients visiting outpatient cardiology clinics at a hospital in Taiwan¹³. The median age was 72 years, 57% were males, and there was a relatively high prevalence of comorbidities, including hypertension (71%), diabetes (35%), and heart disease (45%), reflecting a typical vascular patient population¹³. The deep learning algorithm provides real-time guidance to users, showing them where to place the ultrasound probe on the patient and automatically detects the aorta to measure its maximal diameter¹³. Guided by this software, nurses completed AAA ultrasounds in 37 seconds on average, with 87.5% being of sufficient diagnostic quality, comparable to ultrasound-trained physicians¹³. This technology can improve AAA screening, particularly in underserved areas with limited imaging specialists¹³. While promising, expert human-in-the-loop should be maintained, whereby an ultrasound-trained physician regularly monitors the results to ensure that the AI system is functioning appropriately¹³. Additionally, larger studies in different clinical settings and geographic locations are needed to validate and assess the generalizability of the model's performance¹³. Furthermore, achieving broad clinical impact with new AI technologies requires careful consideration of commercialization strategies, including funding, compliance with safety and regulatory frameworks, health technology assessment, regulatory approval, reimbursement, and clinical guideline integration (Fig. 1).

Opportunities and learnings from the successful commercialization of medical AI technologies

Several companies have successfully commercialized their medical AI technologies, including a US company founded in 2016 focused on neurological care and now expanding to other areas, including cardiovascular, trauma, and oncologic care¹⁴. To date, they have developed several FDA-cleared AI algorithms that analyze medical imaging data across various domains, including CT scans, electrocardiograms, and echocardiograms¹⁴. These tools support clinicians with respect to diagnosis and treatment decision-making for various pathologies, including cerebral aneurysm,

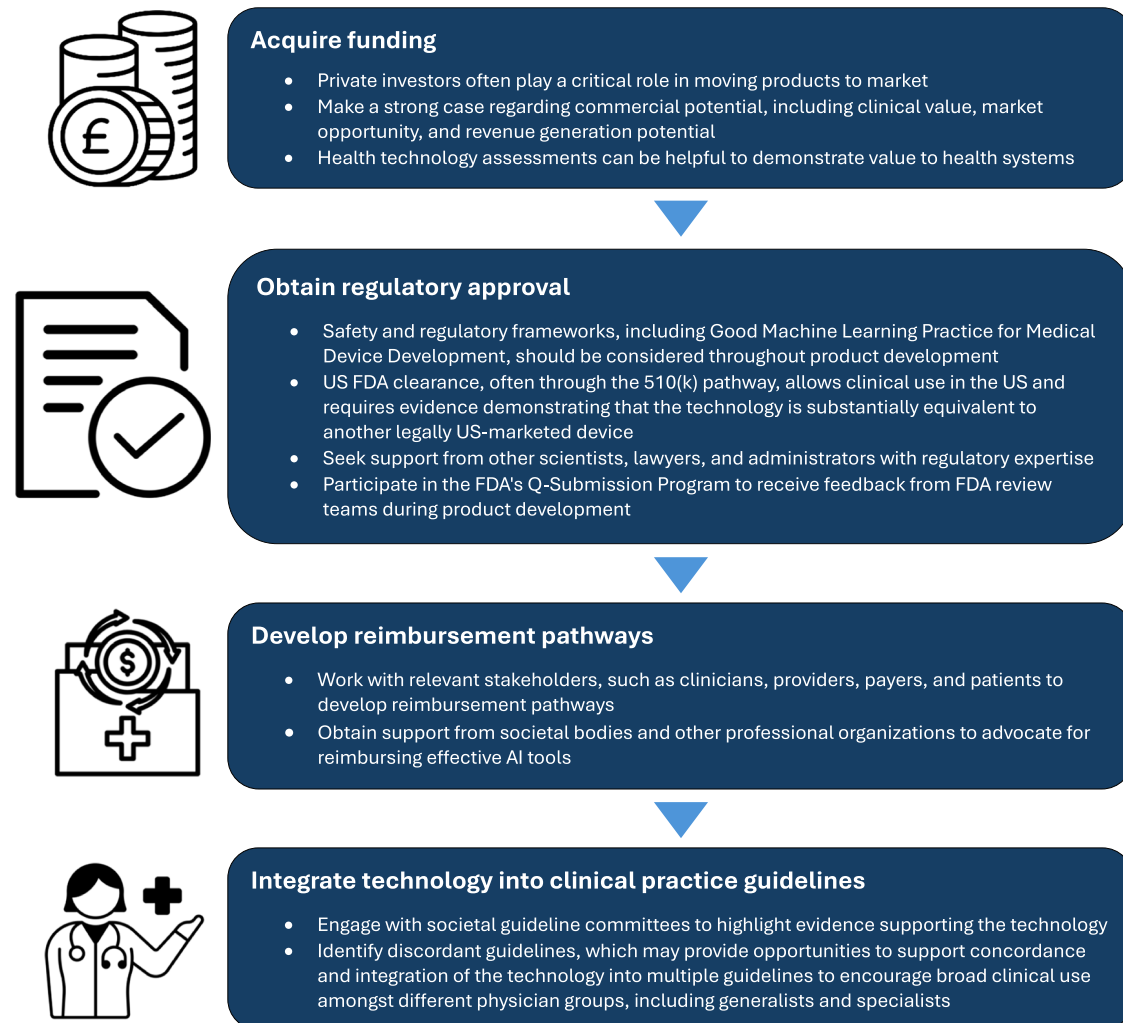


Fig. 1 | Key steps for moving an artificial intelligence product from the research setting to routine clinical practice. US United States, FDA Food and Drug Administration, AI artificial intelligence.

intracranial hemorrhage, ischemic stroke, pulmonary embolism, aortic dissection, and AAA, among others¹⁴. The company successfully built a suite of commercial products, generating revenue over \$40 million in 2024¹⁵.

There were several key factors for their success. First, they assembled a multidisciplinary team of clinicians/engineers who developed robust AI algorithms demonstrated through multiple peer-reviewed publications^{16–20}. In this company, academics worked closely with industry partners and followed standardized approaches for medical device development in a quality management system from the outset, with market and regulatory considerations built in early on through International Organization for Standardization (ISO) certifications²¹. A preliminary health technology assessment demonstrated that such AI tools for ischemic stroke detection could save \$11 million/year in the UK by identifying strokes that otherwise could have been missed²². Resultingly, the company obtained over \$290 million in funding from investors to build and scale their products²³. Using these funds, they developed and refined high-quality AI tools considering regulatory and quality requirements at each step of the process, leading to US Food and Drug Administration (FDA) clearance for their products^{14,24}.

Finally, they worked with the US Centers for Medicare and Medicaid Services to establish new billing codes with a view towards clinical guideline integration, including the use of an AI-based system for ischemic stroke detection at a reimbursement rate of \$1040 per patient^{25,26}. This pathway to reimbursement and coverage is a complex and variable process that typically takes many years and may fail^{27,28}. Therefore, persistence, mentorship, and collaboration are critical to achieve success in translating novel technologies to routine clinical settings^{27,28}.

This company's path can guide investigators like Chiu and colleagues in bringing their AI innovations to market^{13,14}. More broadly, to date, the FDA has approved over 1000 AI medical devices^{29,30}. Therefore, there is a clear opportunity and precedent to obtain regulatory approval for and commercialize medical AI technologies^{29,30}.

Financial, regulatory, and implementation barriers to commercializing medical AI technologies

Investment and funding. Despite the proliferation of medical AI research, few tools achieve the investment needed to reach clinical scale³¹. Academic

grants often end with algorithm development/validation, leaving a funding gap for product scaling/deployment³¹. Private investors play a critical role in bridging this gap³¹. However, they often require more than a high-performing model and seek compelling narratives about health system value and revenue generation potential³¹. Quantitative information regarding clinical impact (e.g., potential number of lives saved vs. comparators) and the nature/scale of the costs saved is often important to investors³². For diseases with relatively small markets, such as AAA's affecting less than 5% of the global population, obtaining private funding can be challenging^{33,34}. Making a strong case regarding commercial potential is therefore critical. For instance, scalable AI-based AAA screening can prevent aneurysm rupture, reducing the costs associated with emergency surgery and saving lives³⁵. Additionally, investors can capture a greater proportion of a smaller and niche clinical market with fewer competitors compared to other relatively saturated markets involving heart disease and cancer, where it may be more challenging for new companies/products to succeed³⁶. Furthermore, the technology can be adapted to other vascular conditions, like carotid, peripheral artery, and venous disease, which also rely heavily on ultrasound imaging for diagnosis and management³⁷. Health technology assessment is essential as it systematically evaluates the cost-effectiveness, safety, and sociocultural implications of new technologies, thereby demonstrating their value to individual health systems³⁸. By highlighting clinical value and market opportunity, investigators improve their chances of obtaining sufficient funding to commercialize their products.

Algorithm development/validation are activities that should take place under guiding principles for Good Machine Learning Practice for Medical Device Development, such as the ones jointly identified by the US FDA, Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency³⁹. When quality frameworks are not followed during product development, retrofitting them to align with regulatory guidelines can be very challenging³⁹. Furthermore, routine and thorough documentation of best practices is critical to facilitate regulatory approval and commercialization³⁹.

Obtaining regulatory approval. Once a product has been developed, regulatory approval is required for broad clinical use⁴⁰. This may be challenging as different jurisdictions often have varying AI regulations⁴⁰. In the US, medical products/devices require FDA clearance/approval for clinical use⁴¹. However, obtaining FDA clearance for AI technologies, often through the 510(k) pathway, can be a significant hurdle requiring extensive data reviews⁴¹. Within the 510(k) pathway, investigators need to demonstrate that their technology is substantially equivalent to another legally US-marketed device⁴¹. Therefore, seeking support from scientists, consultants, and administrators with expertise in regulatory approval, often available at major academic institutions, is critical⁴². Early consultation with the FDA's Q-Submission Program is highly encouraged, allowing investigators to receive feedback from FDA review teams during product development⁴¹. Importantly, regulatory frameworks should be considered at product conception and revisited throughout development, with approval at the end if the process has been adequately followed^{41,42}.

Reimbursement pathways. Most AI tools lack dedicated billing codes and therefore, investigators must work with relevant stakeholders to develop reimbursement pathways to achieve financial sustainability²⁷. Given that billing codes are often well-established, modifying them to include AI technologies may present significant challenges requiring buy-in from multiple stakeholders, including public and private insurers,

clinicians, and patients²⁸. Therefore, early engagement with these groups, often with the support of professional organizations, is essential for successful AI deployment^{27,28}. Importantly, given the complexity of this process, often entangled with the requirement of extensive engagement with stakeholders in different sectors (payers, providers, patients, etc.), it is critical to seek guidance from experienced mentors and actively collaborate with key decision-makers to achieve success^{27,28}.

Integration into clinical practice guidelines. Clinical guideline integration legitimizes AI tools and guides medical practice, which often determines whether new technologies are implemented⁴³. Investigators are encouraged to actively engage with guideline committees to highlight the evidence supporting their technology⁴³. Additionally, investigators should identify discordant guidelines⁴³. For example, the Society for Vascular Surgery recommends AAA ultrasound screening in men/women aged 65–75 with a smoking history or family history of AAA⁸, while the US Preventive Services Task Force (USPSTF) limits their screening recommendation to men aged 65–75 with a smoking history⁴⁴. A key reason for more restrictive USPSTF recommendations is the cost associated with widespread screening of a disease with relatively low prevalence⁴⁴. AI-enhanced AAA screening can reduce costs and increase efficiency, potentially supporting more concordant guidelines^{8,44}. Therefore, engaging with both the SVS and USPSTF may facilitate the integration of AI tools into multiple guidelines to encourage broad clinical use amongst different physician groups, including generalists and specialists^{8,44}. Importantly, given the complex link between clinical guidelines, billing codes, and reimbursement pathways, and the need for all of these to be in place to support broad clinical use of new technologies, it is critical to continuously consider and work towards these various aspects during product conception, development, and implementation^{27,28,43}.

Conclusions and recommendations

Medical AI technologies can improve healthcare and patient outcomes. However, achieving clinical impact requires more than algorithmic accuracy, it demands commercialization strategies that address investment, regulation, reimbursement, and practice integration. With hundreds of AI algorithms published but few adopted, now is the time to focus on the infrastructure and strategy needed for deployment⁴⁵. We urge AI scientists to carefully consider the product to market process to develop AI tools with the greatest potential for clinical impact.

Data availability

No datasets were generated or analyzed during the current study.

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B.L., D.P., and R.L. developed the concept, wrote the paper, and amended the final version.

Competing interests

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Additional information

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