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Belgian position paper on implementing artificial intelligence in cardiology: a roadmap from theory to clinical practice

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ABSTRACT

Artificial intelligence (AI) is rapidly revolutionising cardiovascular medicine, offering significant potential to enhance patient outcomes, streamline clinical workflows, and optimise healthcare resource utilisation. However, integrating AI effectively into routine cardiology practice requires overcoming substantial technical, ethical, regulatory, and economic challenges. This position paper provides Belgian cardiologists, healthcare policymakers, and clinical leaders with a clear, pragmatic roadmap for implementing predictive, generative, and agentic AI technologies. We highlight successful real-world examples, outline precise criteria for clinical validation, propose practical reimbursement strategies, and detail steps to address ethical and regulatory obligations, emphasising AI as augmented rather than artificial intelligence. Our goal is to facilitate the safe, effective, and ethical adoption of AI technologies to augment Belgian cardiology practice.

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Introduction

Artificial intelligence (AI) technologies are rapidly permeating cardiovascular medicine, promising to enhance health outcomes, improve patient safety and reduce administrative burden [1]. As such, there is no doubt that AI will significantly change the way physicians work and medical care is being delivered in the near future. In recent years, major cardiology journals have highlighted early successes with AI, including models that screen for a variety of clinical conditions *via* an electrocardiogram (ECG) [2]. In 2024, over 600 AI algorithms have been cleared by regulators, of which about 10% focused on cardiovascular care mainly in radiology and implantable devices [2,3]. Although AI has considerable potential and is experiencing an unprecedented surge in adoption across the public sphere, its routine clinical integration within cardiology remains limited [2,4,5]. Furthermore, notwithstanding significant recent investments, the European Union (EU) continues to lag behind the United States in embracing AI solutions [6].

Translating AI solutions from bench to bedside revelead significant challenges and many questions are still awaiting an answer. These challenges span the entire lifecycle of an AI solution, from development (e.g. data quality, bias, model design) to deployment (e.g. workflow integration, user trust), and from validation (e.g. clinical efficacy and safety) to maintenance (e.g. monitoring performance post-deployment) (Figure 1). Furthermore, ethical dilemmas around transparency, bias, and accountability are prominent, and regulatory frameworks are only beginning to adapt to the unique characteristics of AI. In addition, economic and reimbursement hurdles further complicate the process of bringing AI tools into daily clinical practice. The rapid advancement of AI solutions surpasses the slower, methodical development of new technologies within evidence-based medicine, prompting a reassessment of established principles to better align these contrasting innovation dynamics. The goal of this paper is to provide a roadmap for clinicians, researchers, and policymakers to navigate the integration of AI into cardiology practice and unlocking its full transformative potential. Throughout this paper, we emphasise clinical relevance, integrate evidence from recent studies, and outline strategies to bridge the translational pathway

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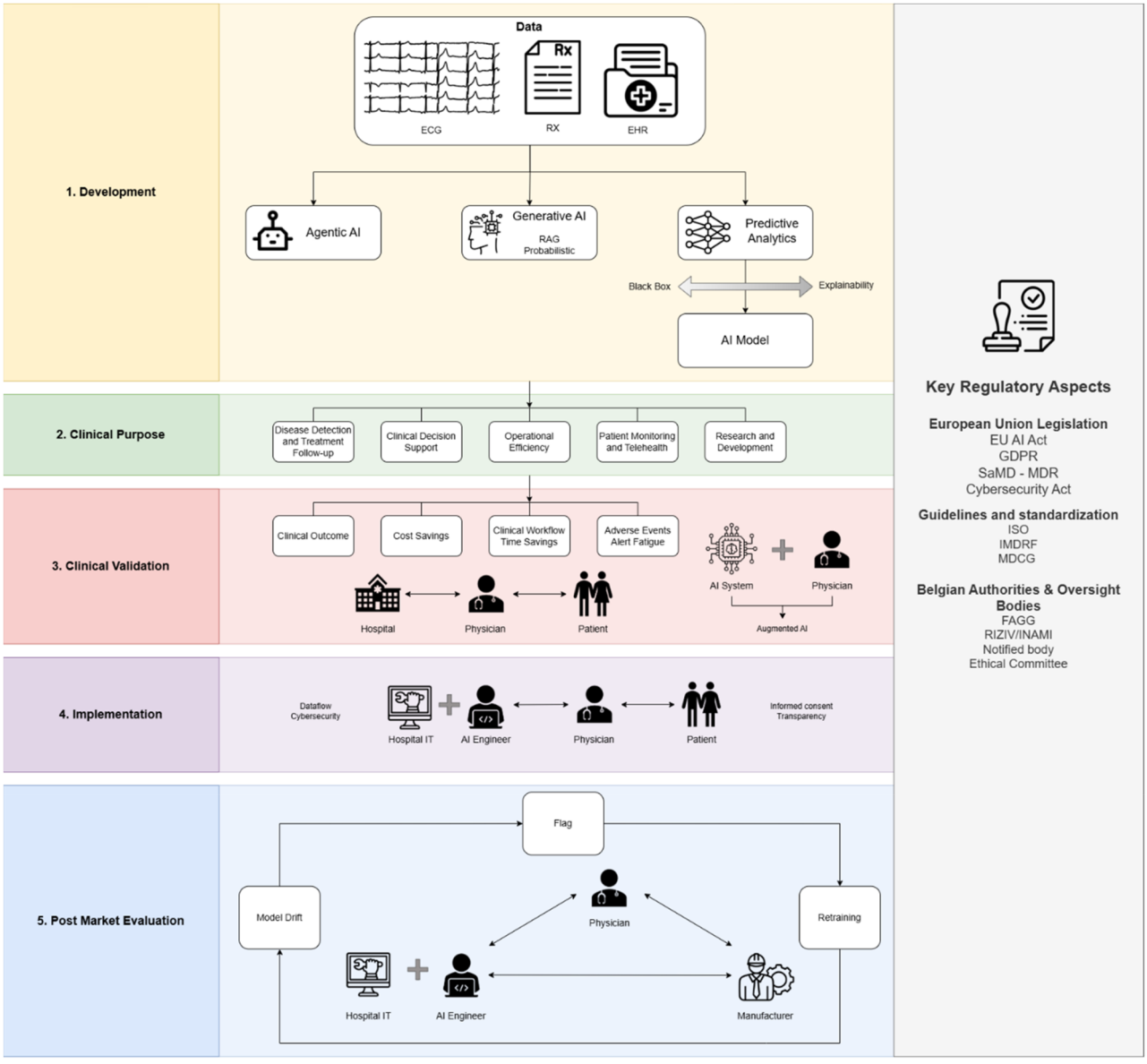

Figure 1. Lifecycle of a medical AI application in cardiology: from development to post-market evaluation.

from AI model development to measurable improvements in patient outcomes.

The basis for this paper was formed by a Digital Health Think Tank supported by Daiichi Sankyo. This initiative convened 20 cardiologists from Belgium, split evenly between the Dutch- and French-speaking region of the country, to brainstorm on the future of AI in cardiology. The insights generated by this brainstorm were further enriched by a review and international literature and finetuned during the 2025 'Future of Cardiology – Gen AI Congress'.

Development, regulatory and clinical integration pathway for artificial intelligence (AI) applications used in cardiology, focusing on Software as a Medical Device (SaMD). The lifecycle is structured across five phases: (1) Development, (2) Clinical Purpose Definition, (3) Clinical Validation, (4) Implementation, and (5) Post-Market Evaluation. Each phase includes key regulatory requirements derived from European and Belgian frameworks. Regulatory references include the EU Medical Device Regulation (MDR), General Data Protection Regulation (GDPR), and the proposed EU Artificial Intelligence Act (EU AI Act). Local oversight and reimbursement pathways are addressed through the Belgian Federal Agency for Medicines and Health Products (FAGG) and the National Institute for Health and Disability Insurance (RIZIV/INAMI).

IMDRF: International Medical Device Regulators Forum; MDCG, Medical Device Coordination Group; AF, atrial fibrillation; PMS: post-market surveillance.

** The AI Act, the first global legal framework on AI, entered into force on August 1, 2024. By employing a*

risk-based approach, it aims to foster trustworthy AI in Europe. The Act will be fully applicable on August 2, 2026, with some exceptions, such as prohibitions on AI systems posing unacceptable risks, taking effect earlier, on February 2, 2025.

A brief introduction to AI in cardiology

AI refers to computational systems that emulate human cognitive functions, such as learning, reasoning and decision-making. In cardiology, three dominant AI paradigms have emerged: predictive, generative and agentic AI.

Predictive AI is often powered by deep learning and analyzes diverse data sources, such as ECGs, imaging, wearables, electronic health records (EHRs), or genomics, to forecast outcomes or detect disease patterns. These models are designed to analyse existing input data to infer or forecast a specific outcome, value or classification, identifying patterns within historical data in order to make 'a prediction'. This enables opportunistic screening, in which an AI solution that is developed for certain target (e.g. detecting a specific biomarker) can also flag unrelated risks (e.g. the identification of coronary artery calcification [CAC] on a chest CT scan that was performed for another reason). For example, AI can identify a reduced ejection fraction or valvular pathology from a standard 12-lead ECG with an accuracy that rivals that of echocardiography [2,7–10]. Machine learning applied to echocardiography can also automate measurements (e.g. volumes, ejection fraction, valve gradients) and flag abnormal findings, potentially expediting diagnosis [2]. Wearable devices, analysed by AI have also been used to predict atrial fibrillation or heart failure exacerbations days in advance, enabling proactive interventions. Multimodal AI integrates disparate data (e.g. imaging, electrophysiology and omics) to refine risk stratificiation, mirroring clinicians' holistic approach [11]. Predictive AI models are deterministic, making them more amenable to validation in traditional clinical trials. However, while retrospective studies showcase high accuracy, prospective trials demonstrating a real outcome benefit are scarce.In addition, generalisability across diverse populations and explainability of these predictive AI models and their output remain an important concern.

Generative AI (or Gen AI) differs from predictive AI in a sense that it creates novel content, such as text, images, or synthetic data, based on existing training inputs [12]. Large language models (LLMs) like ChatGPT can reduce the administrative burden for clinicians by drafting clinical notes (e.g. Cavell.AI), gathering pre-visit data (e.g. Previsit.AI), or answering medical queries. In addition, these models can be used to simplify patient education [13]. Generative adversarial networks (GANs) can produce images thereby improving image quality or fill in missing data, potentially reducing scan times and radiation exposure.

Despite their promise, it is important to understand that generative AI tools are rooted in probabilistic associations rather than objective truths, requiring tailored validation and oversight. In fact, output variability and user misexpectations (e.g. LLM 'hallucinations' or 'confabulations') underscore the need for informed interpretation, ethical use, and validation. For example, an AI-generated clinical summary can sound plausible but may contain subtle inaccuracies that can misguide care if left unchecked. In addition, model transparency and output explainability represent important challenges in the context of Gen AI [12,13].

Agentic AI marks a new frontier in AI, evolving from passive prediction and content generation to systems that are capable of perceiving, deciding, and acting autonomously to achieve defined objectives. Unlike predictive AI, which forecasts, or generative AI, which creates, agentic AI functions independently in a dynamic, real-world environment, guided by reinforcement learning and embodied intelligence [14]. Although long theorised, practical agentic AI applications are only now beginning to emerge. In cardiology, a compelling future scenario involves an autonomous agent that is able to simultaneously analyse ECGs, lab results, vital signs, medication history, and clinical notes to synthesise a comprehensive patient overview in seconds. Nowadays, such a task requires coordination across multiple clinicians.

Looking ahead, the true transformative potential of agentic AI in healthcare lies in its ability to enable highly personalised, proactive care. We can envision systems that continuously monitor patients remotely, adapt treatment protocols in real time, and orchestrate complex, multidisciplinary care pathways, ushering in a new era of intelligent, autonomous healthcare innovation [14].

When selecting AI tools, clinicians should consider predictive AI for assistance in diagnosis or risk stratification, generative AI when they want to create novel realistic content or data, and agentic AI for autonomous task execution. In this respect, the latter requires careful oversight and robust safety protocols.

A glossary of commonly used terms related to AI is depicted in Table 1.

While it is evident that AI holds significant promise for cardiology, the adoption of these tools in everyday clinical practice remains limited (Table 2) [3,15]. To

Table 1. Glossary of commonly used terms related to AI.

Artificial Intelligence (AI)	The capability of machines to perform tasks that typically require human intelligence, such as reasoning, learning, problem-solving, and decision-making.
Agentic AI	AI that actively perceives environments, independently makes decisions, and initiates actions to achieve goals, with minimal human intervention
Deep Learning	subset of machine learning that uses artificial neural networks composed of multiple interconnected layers to automatically learn complex patterns and representations from large volumes of data.
Machine Learning (ML)	A subset of AI in which algorithms enable systems to learn from data and improve their performance over time without being explicitly programmed for each task.
Reinforcement Learning	a type of machine learning where an AI system learns optimal behaviours through trial-and-error interactions with an environment, guided by rewards or penalties based on its actions.
Supervised Learning	A machine learning approach where models are trained on labelled datasets, learning to map inputs to known outputs.
Unsupervised Learning	A machine learning approach that identifies patterns or structures in data without pre-assigned labels.
Neural Networks	Algorithms modelled after the brain's structure, using interconnected nodes (neurons) in layers to process data.
Artificial Neural Networks (ANNs)	Neural networks used in tasks like classification and pattern recognition, mimicking biological neural pathways.
Convolutional Neural Networks (CNNs)	Deep learning models optimised for grid-like data, often used in medical imaging.
Large Language Models (LLMs)	AI models trained on massive text datasets for understanding and generating language (e.g. ChatGPT).
Foundation Models	Pretrained models that can be adapted with minimal tuning for many tasks across domains.
Multimodal Models	Models integrating diverse data types (e.g. text, images, vitals) for richer outputs.
Unimodal Models	Models that analyse a single type of data input (e.g. text only).
Structured Data	Predefined-format data, such as numbers or categories in databases..
Unstructured Data	Data lacking formal structure, such as free text or images.
Hallucinations (in AI)	When AI outputs plausible but factually incorrect or illogical content (also referred to as confabulation).
Wearables	Devices worn on the body to monitor health data like heart rate or activity.

Table 2. Examples (non-exhaustive list) of AI applications by type already used in some cardiology practices in European healthcare systems.Of note, many of these applications still require further clinical validation, integration into existing workflows, and clarification of reimbursement pathways.

Company	Technology	Application	Reimbursement by RIZIV/INAMI
Aidoc, SECTRA Enterprise Imaging, Agfa HealthCare Enterprise Imaging, Canon Medical AiCE (Advanced intelligent Clear-IQ Engine)	AI triage of radiology scans (e.g. pulmonary embolism, stroke), expanding into cardiothoracic CT applications, advanced visualisation and analysis of images, AI modules for cardiology (automated echocardiography measurements)	Clinical decision support, workflow automation	Reimbursement for CT imaging, but no reimbursement for the AI application itself
AliveCor (Kardia), ByteFlies, Rooti Rx	Wearable biosensor platform for AI-enhanced arrhythmia detection	Clinical decision support, remote monitoring integrated in Holter monitoring	Reimbursed within Holter monitoring
Bingli, Infermedica, Previsit.ai	medical assistant platform that enhances medical visits for doctors and patients	Clinical decision support, workflow automation	Not reimbursed
Caption Health (GE HealthCare)	AI-guided ultrasound acquisition to support non-experts in capturing diagnostic cardiac views	Clinical decision support and workflow automation	Not reimbursed
Cardiologs (Philips), Pmcardio, Eko Health	AI powered ECG interpretation	Clinical decision support	Not reimbursed
Cavell AI, Dragon Medical One (Microsoft), Nabla, Noa Notes	LLM-based speech recognition for automated clinical note generation	Workflow automation	Not reimbursed
Cleerly, HeartFlow,	AI-enabled coronary CT analysis	Clinical decision support	Not reimbursed
EchoGo (Ultromics), US2.AI	Automated AI analysis of echocardiography	Clinical decision support	Not reimbursed
FibriCheck	Smartphone photoplethysmography app with AI for atrial fibrillation (AF) detection	Clinical decision support, remote monitoring	Not reimbursed
Lynxcare, Ibis AI	AI platform for clinical data extraction, medical coding and data management	Workflow automation	Not reimbursed
Philips Intellivue Guardian	AI enhanced monitoring tool that calculates Early Warning Scores (EWS) to detect patient deterioration, including cardiac events, allowing for timely intervention and improved patient outcomes	Clinical decision support, remote monitoring	Telemetry is reimbursed, AI application is not reimbursed
Pouya-Heart, Eko Health	AI processing of heart sounds	Clinical decision support	Not reimbursed

overcome this challenge, it is critical to proactively identify and address the barriers preventing clinicians from fully embracing AI. Development must start from the experience and requirements of patients, cardiologists, or healthcare institutions and work backwards towards suitable technological solutions. This patient- and clinician-centric approach helps prevent the creation of technology for its own sake ('tech for tech') and instead promotes tools that deliver 'augmented intelligence', designed specifically to enhance human

intelligence rather than replace or operate independently from it. Collaboration between clinicians and engineers from initial development through post-market evaluation provides a significant opportunity to ensure these tools effectively meet real-world clinical demands. Despite its considerable potential, many physicians continue to view AI sceptically, perceiving it as a semi-scientific buzzword. Therefore, it is essential to approach AI tool development with the same rigorous standards used in cardiovascular drug development, including robust scientific validation, careful selection of appropriate solutions, thoughtful integration into clinical workflows, rigorous efficacy and safety evaluations, secure funding and reimbursement strategies, comprehensive post-marketing assessments, while addressing ethical and regulatory issues throughout the entire life cycle of medical AI applications in cardiology (Figure 2).

Challenges in developing AI models for cardiovascular medicine

Developing robust AI models for cardiology requires the tackling of several technical, clinical, and ethical hurdles.

Data quality, quantity, and diversity

Robust AI models in cardiology depend heavily on datasets that are extensive, of high-quality, and diverse. Unfortunately, however, cardiology data, ranging from electronic health records (EHRs) to imaging and

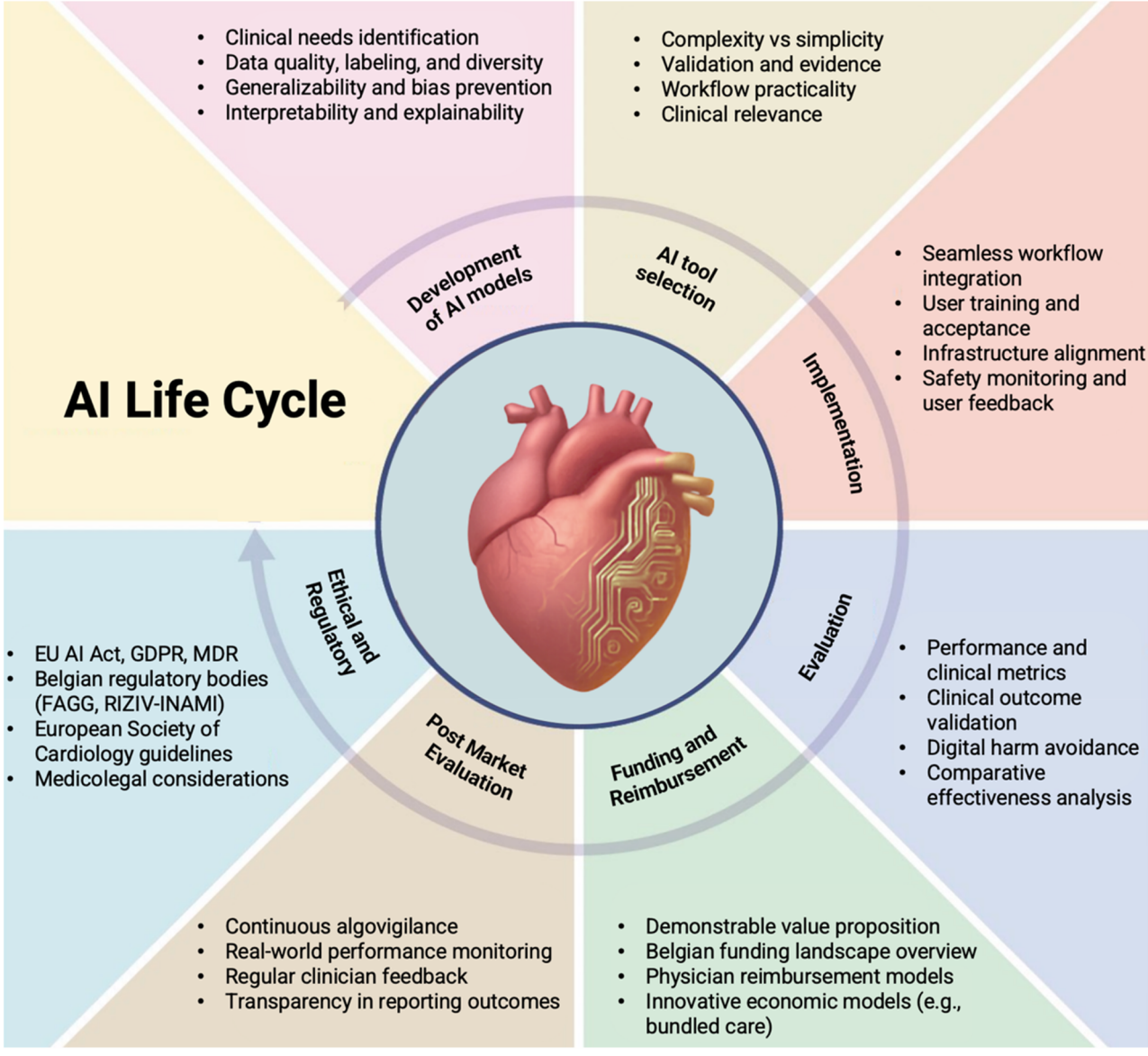

Figure 2. The 7 steps in bringing augmented intelligence from bench to bedside in cardiology.

waveform data (e.g. ECG, echocardiography, CT, MRI), are frequently fragmented, unstructured, and disproportionately representative of specific populations. These issues can limit the generalisability of AI tools and potentially exacerbate existing healthcare disparities. For instance, models predominantly trained on datasets from Caucasian males may exhibit poorer performance in women or minority groups [16]. To overcome these limitations, establishing robust data governance frameworks both within and across institutions is critical. These frameworks should clearly define policies related to data access, quality control, stewardship, and ethical oversight, specifically tailored for the development and deployment of AI models in clinical practice.

Labelling and ground truth

Accurate labelling is critical but often laborious and inconsistent, especially for conditions lacking clear gold standards, such as myocarditis or heart failure subtypes. Noisy labels can mislead models into learning artefacts rather than true pathology [16]. Labelling approaches range from *strong* (e.g. voxel-level annotation of lesions in CT scans) to *weak* (e.g. indicating presence or absence of disease without a precise localization), with the strength of the label having important implications. For example, weak labelling demands more from the model, but in turn also enhances the generalisability of a model across diverse datasets.

Overfitting and generalisability

Complex AI models, particularly deep learning networks, are prone to overfitting. This refers to the memorisation of patterns from training data that fail to generalise beyond it. This is especially common in strongly labelled supervised learning, where models may perform well internally but fall apart when used on external datasets. For example, an algorithm that is trained on ECG data from one hospital may underperform when applied elsewhere. Generalisability of an AI model requires validation across independent cohorts and diverse clinical settings. To establish the real-world utility of an AI model, its generalisability has to be demonstrated empirically.

Transparency, interpretability and explainability

Deep neural networks, though highly performant, often act as 'black boxes', concealing the rationale behind decisions. Techniques such as heatmaps, rule-based outputs, and SHAP (SHapley Additive exPlanations) values can partially illuminate feature contributions and support clinician trust in model behaviour [17,18]. Yet, full transparency is inherently limited in neural networks, just like we cannot trace decisions to specific neurons in the human brain. The key consideration should therefore not be absolute explainability, but rather trust of clinicians in the model. If performance is rigorously validated in clinical trials, trust may ultimately stem from proven accuracy rather than interpretability alone.

Clinical relevance of the problem choice

AI should address genuine clinical needs, not technological novelty. In fact, simple decision rules do the trick in many cases, while the deployment of AI for trivial tasks may add unnecessary complexity. In contrast, however, impactful AI use-cases, such as automating Holter analysis or mass ECG screening, can truly transform care. In this light, it is essential to define clear success metrics and align projects with patient-centered outcomes. Early collaboration with frontline cardiologists ensures clinical relevance and real-world applicability.

Key challenges in AI model development for cardiology include ensuring data quality, addressing bias in datasets, accurately labelling conditions without clear gold standards, preventing model overfitting, and enhancing generalisability across diverse patient populations. With respect to bias and datasets, we emphasise the need for robust data governance frameworks and external validation to counter underrepresentation of demographic groups.Cardiologists and developers must collaborate to prioritise clinically relevant use-cases, implement transparent and interpretable models, and rigorously validate these models across different clinical environments to ensure trust and effective real-world adoption.

Selecting appropriate AI solutions for cardiovascular problems

Given the myriad of AI tools, ranging from simple regression models to complex deep learning and generative systems, clinicians and health systems are faced with the challenge of choosing the most appropriate AI solution for a given cardiovascular problem.

Assess the clinical task and objectives

AI applications in cardiology span the entire care spectrum, from diagnosis (e.g. STEMI detection on ECG) to risk prediction and workflow support. Choosing the right tool starts with clearly defining the clinical task.

Complexity vs. simplicity

Simple models (e.g. logistic regression) may offer comparable performance to complex deep learning systems, with added advantages in transparency, validation, cost, and regulatory approval. In contrast, image or signal-intensive tasks (e.g. echo, ECG) may benefit from convolutional or recurrent networks.

Avoid a one-size-fits-all approach

AI models should be tailored to the task at hand. For example, convolutional networks can be used for imaging, recurrent or transformer models are best suited to analyse sequence data (e.g. ECG), and mixed EHR inputs require a multimodal architecture. In essence, the model should not be more complex than necessary to achieve the intended performance.

Balance performance with practicality

Resource constraints often favour simple models that run locally or *via* cloud services over complex deep learning tools that require graphics processing units (GPUs) and technical expertise. When data are limited, federated learning across institutions can improve performance while preserving privacy. As such, an optimal AI solution should align with the technical capacity and clinical needs of the setting in which it is used.

Validation evidence is essential: Before adopting an AI tool it is important to scrutinise its validity. This is of particular relevance for models that are developed externally. Important questions to ask are: Has the model been tested in a population similar to yours? Was the evaluation prospective? When multiple EMA-cleared tools exist for a given task (e.g. for cardiac MRI), physicians should compare their accuracy and robustness of validation, and evaluate whether there are head-to-head results. Ultimately, AI outputs must be actionable and relevant to the target population.

Workflow and end-user fit

Successful AI adoption depends on user-centered design and clinician involvement. Hospitals should pilot tools, gather feedback, and prioritise solutions that seamlessly integrate into existing systems over standalone applications (e.g. embedding AI into the electronic health record). In this respect, also human factors, such as usability or the need for trainig, are relevant. Poorly matched tools risk underuse and wasted resources, regardless of technical performance.

In summary, selecting appropriate AI tools involves clearly defining clinical objectives and balancing complexity against practicality. Simpler, transparent models often suffice and are preferred unless complexity significantly enhances outcomes, particularly in imaging and ECG analysis. Thorough validation in populations similar to the intended clinical setting and seamless integration into existing workflows are critical considerations to ensure user acceptance and clinical effectiveness.

Implementing AI applications in clinical workflows

Workflow integration

Even high-performing AI models can fail clinically if they are not integrated into existing workflows and health IT systems. Therefore, outputs should appear within familiar platforms, such as EHRs or PACS (Picture Archiving and Communication System), to avoid workflow disruption. This includes direct embedding of AI-generated insights into the EHR as decision support or pre-populated documentation, and overlaying findings directly onto images in PACS with automated report generation. For instance, an AI tool that analyzes ECGs should deliver results directly in the standard viewer or report template of the cardiologist, without the need for separate logins. Initial 'silent mode' deployment allows clinicians to observe AI outputs without altering decisions, supporting gradual adoption. Crucially, downstream validation of EHR data is essential to safeguard input quality and avoid the 'garbage in, garbage out' effect.

Socio-technical integration and change management

Successful AI implementation in cardiology relies equally on people and technology. Proactive engagement of all stakeholders (i.e. clinicians, nurses, allied health professionals, IT staff, and hospital administration) from the earliest stages of AI selection and planning is essential to foster ownership and commitment. Clear communication strategies must articulate the rationale behind AI adoption, explicitly detailing expected benefits while openly addressing potential concerns or resistance related to changes in established workflows. For example, users must understand that AI can assist but is not infallible (e.g. ECG interpretation). Additionally, identifying clinical champions or super-users within cardiology departments can significantly drive adoption, provide essential peer support, and facilitate ongoing feedback. Recognising AI implementation as a socio-technical transformation, rather than merely a technological update, underscores the necessity for thoughtful workflow redesign, role adjustments, and comprehensive support through robust change management practices.

Workflow shifts: AI has the potential to significantly reduce the cognitive and administrative burden of clinicians, nurses or technicians by automating routine tasks, such as measurements and reporting. This allows physicians to focus on interpretation and patient care, as shown in the AI-ECHO randomised trial [19]. However, in other settings, AI may also introduce new tasks, increasing the workload and the risk for alert fatigue (e.g. reviewing alerts in remote heart failure monitoring by the heart failure nurse). To realise the full promise of AI, deployment must prioritise reducing low-value tasks while safeguarding users from information overload.

Interoperability and IT support

Seamless AI integration requires an IT infrastructure with sufficient hardware capacity, supporting HL7/FHIR standards and GDPR compliance. Ongoing collaboration between clinicians, IT teams, and vendors is essential to ensure reliable performance, regular updates, and cybersecurity. AI implementation is not plug-and-play, but demands continuous technical support and system alignment.

Redesigning clinical workflow

protocols, such as AI-driven emergency department triage for chest pain, can optimise resource use, but demands protocol updates and staff training as well as regulatory or administrative approval within the institution.

Safe and iterative implementation

Checkpoints (e.g. double-checking of outputs) during AI rollout protects patients, while transparency about the role of the AI tool fosters trust. Therefore implementation should be incremental and continuously informed by user feedback, performance, and outcomes. In doing so, we can ensure that AI augments rather than compromises care. As such, careful planning, training, and staged deployment are essential for a safe clinical integration of AI.

In brief, effective AI implementation into clinical workflows requires embedding AI outputs into existing platforms (EHR, PACS) to minimise disruptions. Hospitals should adopt iterative implementation strategies, starting with 'silent mode' deployments to build clinician trust. Providing targeted training and carefully redesigning workflow protocols are essential to ensure user buy-in, manage workload changes, and mitigate alert fatigue, thereby enhancing overall efficiency and clinician acceptance.

Evaluating efficacy and safety of AI systems

Evaluating an AI tool in cardiology is multi-dimensional, spanning from technical validation, over clinical impact, to safety, and fairness [20,21].

Performance metrics (technical efficacy): To assess the real-world clinical impact of an AI model, its evaluation must go beyond metrics such as sensitivity, specificity, or area under the curve (AUC). While many models achieve high AUCs in internal validation, this performance often declines when the model is deployed externally (mainly the positive predictive value of the tool). The latter is of particular relevance if the AI tool is used in populations with lower pre-test probability. This highlights the necessity of independent, external validation to ensure generalisability and clinical utility.

Clinical validation and outcome studies, ideally through prospective randomised controlled trials, which are vital to confirm improved clinical outcome over standard care (e.g. faster diagnoses or reduced readmissions) [22]. While prospective outcome trials remain scarce, EU HTA frameworks to support large-scale validation are under development. Importantly, the balance between sensitivity and specificity can be adjusted depending on the clinical context (Figure 3). For example, high sensitivity and a high negative predictive value might be prioritised in case of a screening AI ECG as this avoids missing disease. The cost of some false positives may be acceptable here (e.g. cardiac amyloidosis). In contrast, for tools that steer invasive decisions (e.g. sending someone to cath lab), a high specificity is more important.

Safety and error analysis

Rigorous evaluation is essential to ensure that AI benefits patients without causing 'digital' harm [23]. In this light, the safety of an AI tool must be measured against the adverse outcomes (such as costly diagnostic tests or risky invasive procedures) it may induce due to false positives or negatives. For instance AI ECG may improve the detection of occlusion myocardial infarction, but this has to be weighed against a number of unnecessary cathlab procedures in case of a lower positive predictive value (as illustrated in Figure 3).

The randomised comparison evaluates two clinical pathways: standard clinical assessment (without AI) versus AI-supported diagnosis. Primary outcomes include mortality and myocardial damage due to missed diagnoses, as well as the associated costs and risks from unnecessary catheterisation procedures driven by false positives. This figure highlights the critical clinical trade-off between sensitivity gains (detecting more OMIs) and specificity losses (increased unnecessary

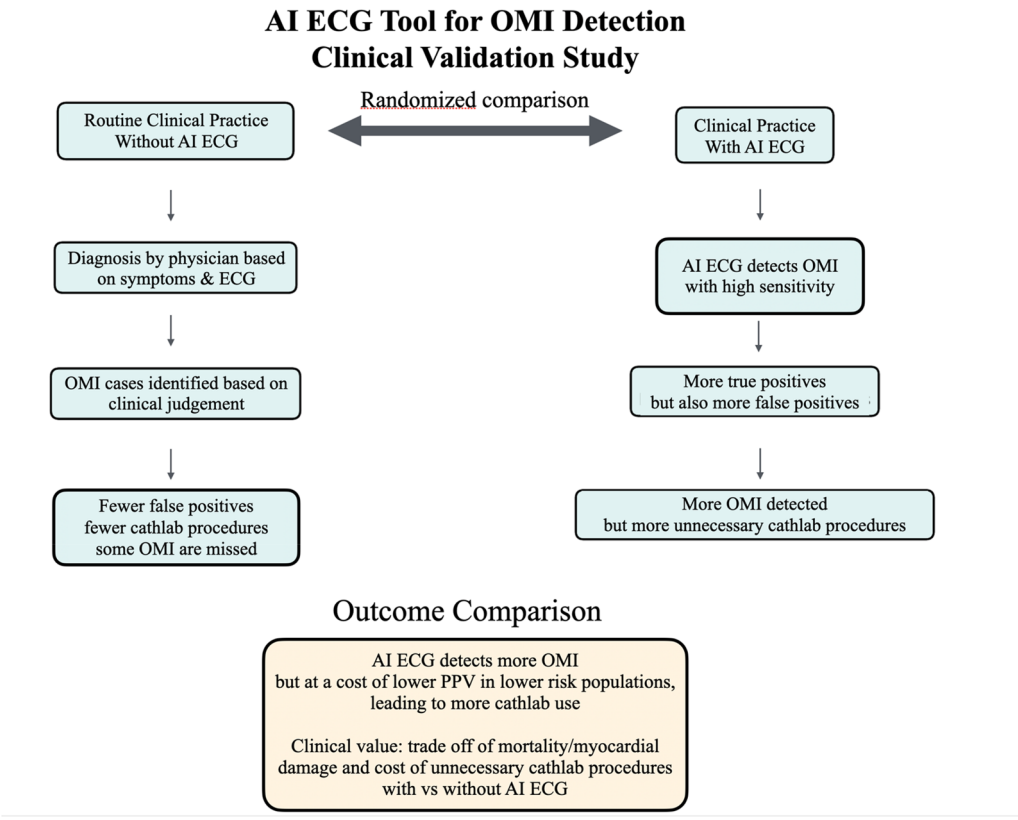

Figure 3. Conceptual design for a clinical validation study assessing the impact of AI-enhanced ECG for Occlusion Myocardial Infarction (OMI) detection in the emergency department.

interventions) when incorporating AI tools in routine emergency care (PPV: positive predictive value).

Bias and fairness

To ensure equitable accuracy of an AI tool, its performance must be stratified by demographics (e.g. sex, age, ethnicity). For example, does a heart failure risk model perform equally in women and socioeconomically disadvantaged groups?

Comparative effectiveness: AI should be benchmarked against standard care or existing risk scores. For imaging tools, reader studies comparing clinician performance with and without AI support help to assess its added value in a real-world setting [21]. In essence, the ultimate goal of AI should always be to meaningfully improve clinical decision-making.

Guidelines and reporting standards

Frameworks such as SPIRIT-AI, CONSORT-AI, STARD-AI, DECIDE-AI, and PROMISE enhance rigour and reproducibility in AI research [24–28]. These frameworks provide guidance with respect to designing, conducting and reporting AI clinical studies (e.g. were models locked, outcomes adjudicated, and analyses prospective), the provide standards for diagnostic accuracy studies and performance metrics, or offer guidance on the clinical evaluation of the impact and clinical role of AI-based clinical decision support systems (e.g. standards for evaluation of clinical performance and effectiveness of AI systems,). As such, these frameworks help to improve the scientific, regulatory, and clinical credibility of AI tools [20].

In summary, evaluating an AI tool in cardiology is multi-dimensional and includes a technical validation in conjuction with an assessment of its clinical impact, safety, and fairness. Efficacy is not just about predictive accuracy but also means that the tool improves real-world patient care. Safety requires vigilance for errors and biases. The endgame is to prove that an AI tool is effective, safe, and reliable enough to ensure that its benefits outweigh any potential risks. This is essential to earn the trust of clinicians, patients, and regulators. Only when an AI tool is backed by such a level of evidence it can move from experimental or observational use to routine clinical care.

Funding models and reimbursement strategies for AI in cardiology

Economic viability remains a critical barrier for AI adoption, raising key questions on who should fund

the development, deployment, ongoing maintenance, and clinical oversight of AI tools. High costs associated with data curation, validation, regulatory approval, and IT integration are typically funded through internal investments, grants, industry partnerships, or venture capital-backed start-ups. For instance, a hospital investing in AI for automating cardiac MRI documentation could reallocate salary savings from reduced technician workload to fund AI licences. However, existing reimbursement models from payers (e.g. insurance companies, RIZIV/INAMI) traditionally cover procedures, visits, or clearly defined services, leaving algorithm-based analyses often unreimbursed as standalone services.

A specific challenge lies in the development of economic models that recognise and appropriately reimburse the synergistic value of 'augmented intelligence' (i.e. where AI tools enhance rather than replace clinician expertise). Traditional fee-for-service models typically do not capture this combined value, underscoring the need for innovative approaches that recognise enhanced efficiency, improved diagnostic accuracy, or more personalised treatment planning achieved through clinician-AI collaboration, rather than separately reimbursing clinician time or AI usage.

Value proposition and reimbursement

To justify funding, AI solutions must clearly demonstrate both clinical and economic benefits. For example, AI-enabled ECG screening that identifies patients with low ejection fraction early can prevent costly hospitalisations through timely interventions. If per-patient AI costs are significantly lower than potential savings from reduced admissions, reimbursement becomes economically justified. Without clearly demonstrated value, AI tools risk remaining unfunded, with healthcare providers absorbing upfront costs in anticipation of future efficiencies or improved outcomes.

Regulatory and funding landscape

Regulatory approvals (e.g. FDA, MDR, FAGG, CE-mark) are crucial yet costly due to extensive validation and documentation requirements, potentially raising AI pricing and hindering widespread adoption. In Belgium, support for AI development comes through initiatives like the Flemish AI plan (VLAIO), Flemish Research Foundation (FWO), Innoviris in Brussels, and DigitalWallonia4.ai programs (e.g. Start IA, Tremplin IA). Additionally, EU funding programs such as Horizon Europe and IHI provide subsidies aimed at fostering AI research and long-term health system efficiency, often in collaboration with RIZIV/INAMI and Sciensano.

Physician reimbursement

Current fee-for-service models tie physician reimbursement to volume rather than efficiency, creating structural disincentives for the adoption of efficiency-enhancing AI tools. In fact, AI-driven time savings may inadvertently reduce physician compensation if patient volumes do not increase. Transitioning towards value-based reimbursement models, rewarding improved outcomes rather than procedure volume, will be essential to create incentives and support the widespread integration of AI.

Innovative funding models

Alternative reimbursement strategies such as bundled payments, flat-fee subscriptions, or pay-for-performance models can enhance the financial sustainability of AI tools. For instance, AI-driven heart failure telemonitoring that demonstrably reduces hospitalisation rates could justify a bundled payment approach by RIZIV/INAMI, indirectly funding the AI service. These stratgeies are crucial to recognise the synergistic value of augmented intelligence by shifting the focus from individual components (i.e. clinician time or AI usage) to the combined value of enhanced efficiency and improved diagnostic accuracy. Innovative reimbursement approaches, supported by organisations like the European Society of Cardiology, are crucial for ensuring financially viable pathways for proven digital health tools. Without aligned incentives or clear economic benefits, even clinically effective AI solutions may struggle to scale within financially constrained healthcare environments.

European projects in the field

In this complex landscape, there are two founded European projects: ASSESS DHT is a European initiative that will increase the adoption of trustworthy and effective Digital Health Technologies (DHTs) across Europe, enabling a more coherent digital single market, for health systems and patients to access DHTs from all over Europe and giving industry a European market. The objective is to develop robust and harmonising methodologies for Health Technology Assessment of Digital Health Technologies with the European Health Data Space regulation [29]. On the other hand, EDiHTA will be the first validated and ready-for-use European HTA framework allowing the assessment of different DHTs like AI, telemedicine, mApps at different Technology Readiness Levels, territorial levels (national, regional and local) and perspectives like payers, societies, hospitals [30].

In conclusion, while clinical efficacy remains paramount for the adoption of AI, its economic viability is

essential for scalability. In cardiology, a setting in which conditions such as myocardial infarction and heart failure can drive high costs, AI can demonstrate value by improving outcomes and reducing admissions. Innovative reimbursement models (bundled payments, pay-for-performance) and institutional funding strategies can support financial sustainability. Clearly aligning AI adoption with value-based healthcare principles and proven cost-effectiveness will incentivise adoption and scalability in Belgium.

Post-marketing and post-deployment evaluation of AI tools

Unlike traditional drugs or devices, AI algorithms are inherently dynamic, capable of evolving through regular updates or continuous learning. Consequently, their performance may degrade over time due to changes in clinical practices, patient populations, or data quality. These issues are collectively known as model drift. For instance, an ECG-based AI may lose accuracy in diagnosing myocardial infarction if diagnostic criteria shift or input quality declines, increasing the risk of errors and reinforcing the 'garbage in, garbage out' effect. Regular performance monitoring, annual re-validation, and clinician feedback (e.g. tracking recurring errors in echocardiography AI interpretation) are crucial to safeguarding clinical reliability.

Furthermore, the field is advancing towards AI models that are capable of continuous or online learning, dynamically adapting based on newly acquired data post-deployment. While this approach is promising, it introduces substantial challenges for ongoing validation, regulatory oversight, and risk management, ensuring that incremental updates do not inadvertently degrade model performance or introduce new biases. Future regulatory and monitoring frameworks must evolve to effectively manage these dynamic algorithms in real-time clinical settings.

Under the EU AI Act, post-market surveillance for high-risk AI systems, including mandatory reporting of serious incidents to authorities such as FAGG, mirrors existing pharmacovigilance frameworks [31,32]. Institutions that substantially alter deployed AI systems may be reclassified as manufacturers under the Medical Device Regulation (MDR), subjecting them to full regulatory requirements [31–33]. Publishing real-world performance data, including metrics such as false-positive rates in ECG screening, enhances transparency and builds clinician and patient trust. Ultimately, ongoing 'algovigilance' (i.e. continuous monitoring and reporting akin to phase IV drug surveillance) is essential to maintain the efficacy, safety, ethical compliance, and patient protection of AI tools throughout their clinical lifespan. Operationalising algovigilance effectively will necessitate clear institutional protocols and dedicated resources. This includes defining responsibilities for monitoring (e.g. a multidisciplinary AI review board), establishing performance thresholds or specific triggers that prompt re-evaluation (e.g. significant shifts in patient demographics, changes in input data characteristics, detection of systematic errors by clinicians), and implementing standardised reporting mechanisms for AI performance and safety incidents, akin to pharmacovigilance. These triggers and re-evaluation processes are often guided by international standards and recommendations from ISO, IMDRF, MDCG, forming a continuous feedback loop with regulatory checkpoints.

In summary, AI deployment only marks the beginning of its evaluation. Continuous monitoring and regular re-validation ('algovigilance') are crucial to maintain AI performance post-deployment. Institutions must systematically monitor for performance drift, integrate clinician feedback, and adhere to mandatory reporting of incidents to regulatory bodies. Regular updates and transparent reporting of real-world data foster trust and ensure sustained clinical safety and effectiveness. The interaction of these regulatory checkpoints (Figure 1) provides the legal, ethical, and operational scaffolding for this robust post-market surveillance, ensuring algovigilance is a systematically implemented and legally enforceable process.

Ethical and regulatory considerations in AI adoption

Navigating the complex regulatory landscape surrounding AI adoption in cardiology demands structured and early engagement with national and European Union (EU) frameworks. Figure 4 presents a clear decision tree tailored to the Belgian context, precisely delineating when AI-based software qualifies as a medical device and outlining the requirements for CE-marking and notification to Belgium's Federal Agency for Medicines and Health Products (FAGG). By translating EU Medical Device Regulation (MDR), General Data Protection Regulation (GDPR), and the forthcoming AI Act obligations into practical, step-by-step guidance across distinct development stages (from exploration to clinical deployment), this visual tool provides essential clarity for clinicians, researchers, and regulatory personnel involved in AI integration into cardiology practice.

This diagram details the regulatory decision-making process for classifying AI software under the EU

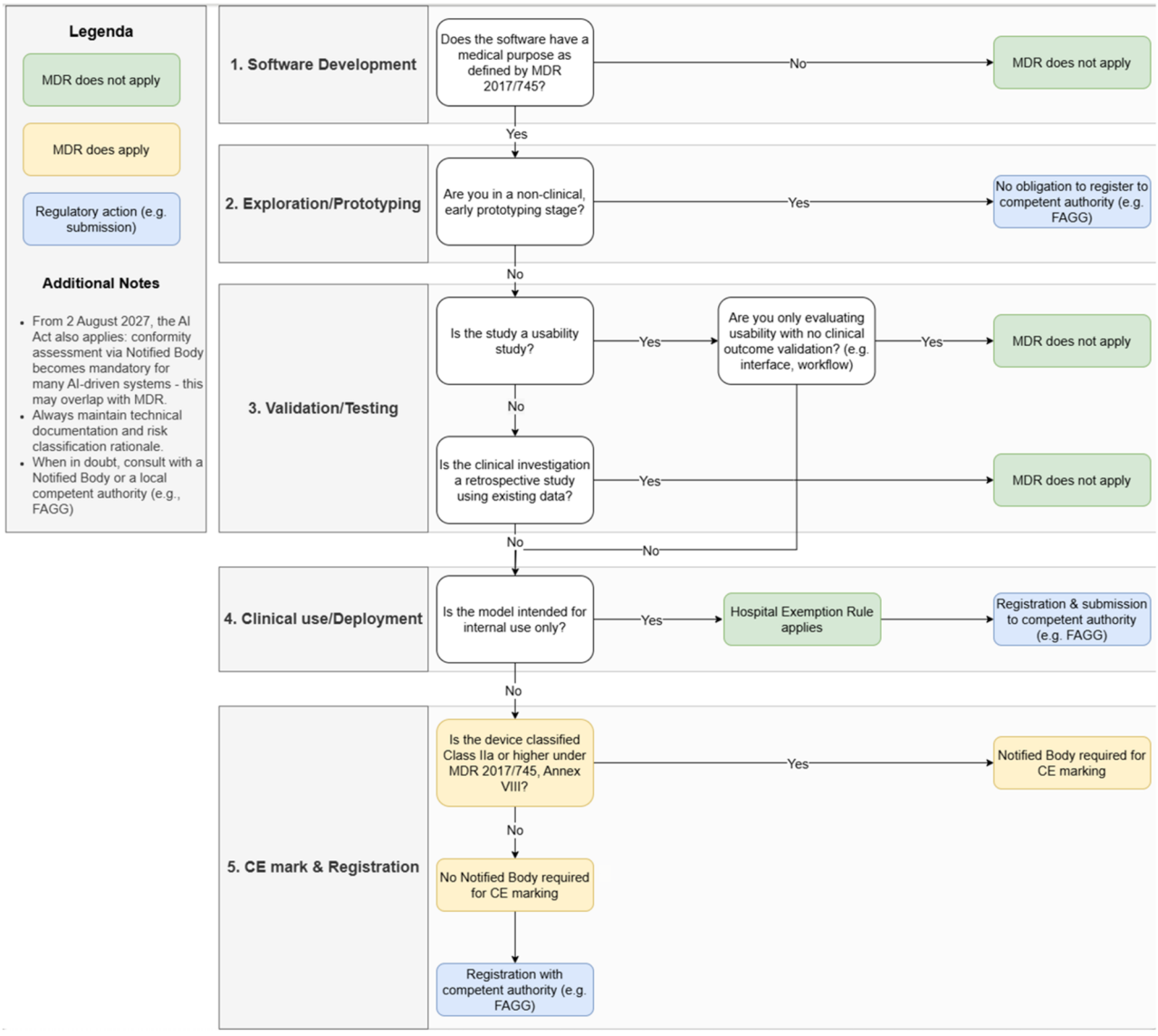

Figure 4. Regulatory decision tree for AI-based medical software in Belgium.

Medical Device Regulation (MDR). It delineates clearly between exploratory phases, prototype testing, clinical investigations, and deployment phases, indicating when MDR compliance, CE-marking, and registration with Belgium's Federal Agency for Medicines and Health Products (FAGG) are required. It also clarifies hospital exemption rules, usability studies, retrospective validation and CE mark implications, providing a structured overview of the ethical and regulatory steps relevant to AI integration in clinical practice.

Bias and transparency

Ethical AI in cardiology demands fairness, transparency, and patient trust. Diverse training datasets (e.g. including women, minorities, and older adults) are essential to mitigate bias [20]. To ensure autonomy in shared decision-making, patients and clinicians must understand the supportive role of AI. This requires a clear disclosure when an AI tool informs decisions. In this light, the EU AI Act emphasises algorithmic transparency, explainability, interpretability and accountability in high-stakes healthcare settings [32].

Privacy and consent

Cardiac AI heavily relies on personal health data, including imaging. While GDPR governs data protection, full de-identification is often impossible (e.g. imaging with identifiable features). This raises unresolved questions on what constitutes personal data in AI training as well as ethical concerns regarding data sharing. Multi-centre projects (e.g. pooled ECG datasets) require robust de-indentification, consent and institutional transparency. **Accountability:** it is important to acknowledge that legal responsibility remains

with clinicians and institutions. If an AI ECG tool misses an acute myocardial infarctionor is overruled incorrectly, liability must be clearly defined. While advisory use remains the norm, proposals for liability shields or AI-specific insurance are emerging. Awaiting the maturation of formal frameworks, clinicians remain the final arbiters and human oversight remains essential [20].

Augmented, not artificial intelligence

AI should not replace, but enhance the patient-clinician relationship (e.g. enabling more accurate risk communication, empowering patients in shared decision-making).

Evolving EU regulation

The Medical Device Regulation (MDR) and the upcoming EU AI Act classify most diagnostic AI tools as high-risk, requiring independent validation, robust risk management, and comprehensive post-market surveillance [31–34]. Developers and healthcare institutions should be aware of the critical interplay between the MDR and the EU AI Act. For AI systems qualifying as medical devices, particularly those deemed high-risk, manufacturers will need to navigate the requirements of both regulations, which may involve distinct conformity assessments, risk management processes, and post-market surveillance obligations. Clarity on how these two frameworks will be synergistically applied to Software as a Medical Device (SaMD) is crucial for efficient and compliant innovation. AI systems that solely focus on administrative tasks, such as medical text classification or data structuring, are less likely to be classified as high-risk unless they directly influence clinical decisions. Generative AI systems (e.g. large language models) face distinct transparency requirements monitored by the EU's new AI Office [35]. Belgium's 2024–2029 federal government accord aligns with these principles, emphasising augmented intelligence and strengthened physician-patient relationships. The EU's ethics-by-design concept ensures developers embed fairness, explainability, and accountability from inception. ISO standards (e.g. ISO 23894) and ESC-led initiatives (e.g. CORE-MD) further support alignment with European regulatory expectations [31]. In cardiology, AI tools that affect diagnosis or treatment qualify as regulated medical devices, unlike internal quality-improvement or general wellness apps without medical claims. Clinicians must be fully aware of the regulatory status of the AI tools they employ. In fact, utilising unapproved AI outside research contexts carries medicolegal risks with ultimate responsibility resting on the physician. MDR compliance mandates a detailed post-market surveillance plan, and any deviation from approved models (e.g. silent updates) requires proper documentation. Regulatory audits may verify consistency between deployed and approved AI models. Clinicians and IT departments must maintain accurate records of software versions, and all AI-related safety incidents must be promptly reported to authorities (e.g. FAGG). Promoting a safety culture around AI is vital for regulatory compliance and ethical practice. Ongoing efforts towards international AI regulation harmonisation (e.g. IMDRF) continue, but regional differences persist, impacting international collaboration and cross-border care.

Stringent and costly regulatory requirements may slow the development and clinical adoption of AI tools. To address this, the European Medicines Agency (EMA) established the PRIME (PRIority MEdicines) initiative, which provides enhanced regulatory support for the development of treatments, including AI-based tools and digital therapeutics, that target unmet medical needs [36]. This initiative offers early scientific guidance, facilitates accelerated assessment, and supports faster access to innovation for patients. For example, an AI-powered ECG tool that improves the early detection of occlusion myocardial infarction (OMI) could be considered for PRIME support if it demonstrates the potential to significantly reduce diagnostic delays and improve clinical outcomes in populations lacking effective diagnostic solutions. The recent reimbursement framework introduced by the National Institute for Health and Disability Insurance (RIZIV) for telemonitoring in heart failure patients exemplifies how structured care pathways can facilitate the integration of AI technologies into clinical practice. Under this model, patients monitor parameters such as weight and blood pressure at home, transmitting data *via* certified health applications. These applications, which must be CE-marked medical devices, analyse the data using patient-specific thresholds, enabling timely interventions by healthcare providers. While the reimbursement specifically covers telemonitoring services, it inherently supports the adoption of AI-driven solutions that enhance data analysis and alert management. This approach not only improves patient outcomes but also demonstrates how bundled payment models can accelerate the integration of AI into reimbursed care trajectories, setting a precedent for broader applications in cardiovascular medicine.

In brief, while AI advancements in cardiology are accelerating, the slower evolution of ethical, regulatory, and reimbursement frameworks presents a significant challenge. Ensuring fairness, transparency, and respect for patient rights is essential to avoid digital

harm. Robust oversight throughout the AI lifecycle will be key to maintain safety and trust. To this end, stakeholders must proactively integrate rigorous ethical standards, transparency, and patient rights protection into AI model development (i.e. building trustworthy AI). This will prevent that the 'AI hype' outpaces its safety net and ensure that the integration of AI in cardiology is done in a way that is consistent with the profession's commitment to patient welfare and evidence-based practice.

Conclusion and future directions

AI is poised to become a transformative force in cardiovascular medicine, empowering and augmenting clinicians, nurses, and patients, enhancing value-based care, and supporting a more personalised, efficient, and proactive delivery of cardiovascular healthcare. From expert-level ECG interpretation to predictive analytics and workflow automation, its potential to improve outcomes and reduce costs is substantial. However, realising this promise requires more than technical excellence.

We urge the Belgian healthcare ecosystem, including the funding agencies (VLAIO, Innoviris), regional innovation platforms (e.g. DigitalWallonia), technology developers, both hospital-integrated and external industry partners, Federal Public Service Health, RIZIV/INAMI, FAGG, academic institutions, professional societies, and patient advocacy groups, to act in concert. Rigorous, real-world validation must become the standard for AI tools, in which evidence generation keeps pace with the rapid development of new AI solutions. In parallel, regulatory and reimbursement frameworks must evolve to support a safe, effective, and equitable integration of AI. The latter is amply illustrated by promising steps such as the recent telemonitoring reimbursement or the EMA's PRIME initiative.

Clinicians must remain at the centre of care, taking final responsibility and oversight, but supported by tools that reduce administrative burden and amplify their impact. Patients must be informed partners, benefiting from AI that is able to enhance rather than replace 'the human touch'. AI also holds unique promise for empowering patients through clearer communication, early diagnosis, and more active participation in their own care.

To ensure clinical relevance, seamless integration, and long-term success, AI solutions must be co-developed through continuous collaboration between physicians, engineers, and data scientists across the entire AI lifecycle, from model conception to post-market evaluation (Figures 1 and 2). This interdisciplinary approach is essential to ensure that AI tools are clinically meaningful, usable, and safe.

Equally critical is the integration of AI applications into existing hospital systems, such as electronic health records (EHR) and picture archiving and communication systems (PACS). Without seamless interoperability and embedding of AI outputs into routine clinical workflows, even the most accurate tools risk underuse or clinical inefficiency. For AI to truly add value at the bedside or in the cath lab, it must function within the platforms clinicians already rely on.

In building this future, the focus should always be on outcomes, not algorithms. The cardiology community must now shape AI tools that are transparent, trustworthy, and tailored to clinical reality, backed by robust evidence and rooted in shared ethical standards. To achieve this, establishing a dedicated 'AI in Cardiology Committee' in Belgium is essential. This committee would bring together cardiologists to leverage their collective expertise, systematically assess AI applications against rigorous quality criteria, verify regulatory compliance, and determine their genuine added value for clinical practice and patient outcomes. By promoting knowledge sharing across hospitals and facilitating collaboration with technology companies developing cardiology-focused AI solutions, such a committee can ensure that AI does not replace physicians, but augments both care delivery and patient experience, solidifying AI as a cornerstone of future cardiovascular practice in Belgium and beyond.

Key take home messages

- AI tool development must be clinician-driven, prioritising the augmentation rather than replacement of clinical judgement.
- Prospective clinical validation is non-negotiable to facilitate meaningful and safe adoption of AI in clinical practice.
- Innovative reimbursement models are essential to ensure the economic viability and scalability of AI solutions in healthcare.
- Seamless integration of AI tools in electronic health records (EHRs) and PACS workflows is critical to achieve sustained clinical adoption.
- Regulatory frameworks must proactively evolve in parallel with the rapid AI development to ensure timely patient access without compromising safety.
- Continuous post-deployment monitoring ('algovigilance') is vital to sustain efficacy, safety, and trust among clinicians and patients.

- Transparency, accountability, and proactive bias mitigation are essential for equitable AI implementation, safeguarding trust in healthcare delivery.

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