

HRS scientific statement on artificial intelligence integration framework into clinical electrophysiology workflows

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ABSTRACT

Artificial intelligence (AI) and digital health technologies (DHTs) are rapidly transforming health care, offering unprecedented opportunities for enhanced diagnostics, treatment, and patient management. However, such boundless potential brings new challenges for regulatory bodies, administrators, and ultimately clinicians to identify points of integration of AI/DHT into clinical workflows. Specifically, clinicians must understand where AI/DHT can be safely integrated within the clinical care process, what resources are available to guide decisions about adopting new AI/DHT methods, and how to monitor and adjust the implementation strategy through real-world use. Highlighting both existing and potential new AI/DHT applications within the space of clinical electrophysiology, this statement identifies the resources and various available frameworks to guide adoption of AI/DHT and strategies for continuous monitoring, recalibration, retraining, and, if necessary, cessation of use. We emphasize the critical importance of data interoperability for integrated care and the ethical imperative to address data protection, bias, transparency, and accountability. Ultimately, responsible implementation, vigilant post-deployment evaluation, and adherence to human rights principles are essential to harness AI's full potential for equitable and personalized patient care.

KEYWORDS Artificial intelligence; Clinical electrophysiology; Digital health; Workflows

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ABBREVIATIONS AI = artificial intelligence; AMA = American Medical Association; CMS = Centers for Medicare & Medicaid Services; CPT = Current Procedural Terminology; DHTs = digital health technologies; ECG = electrocardiogram; EHR = electronic health record; EP = electrophysiology; EU = European Union; FDA = Food and Drug Administration; HRS = Heart Rhythm Society; IMDRF = Inter-

national Medical Device Regulators Forum; LLMs = large language models; MHRA = Medicines and Healthcare products Regulatory Agency; ML = machine learning; Pre-Cert = Software Precertification; RE-AIM = Reach, Effectiveness Adoption, Implementation, Maintenance; SaMD = Software as a Medical Device

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Introduction**Preamble**

The Heart Rhythm Society (HRS) has developed scientific and clinical documents guiding the management of cardiac arrhythmias since 1996. This HRS statement discusses the process of artificial intelligence and digital health tools integration into clinical electrophysiology (EP) workflows.

Editorial independence

The statement is sponsored by the HRS and was developed without commercial support. All writing committee members and peer reviewers volunteered their time to the writing and reviewing efforts.

Organization of the writing committee

HRS has rigorous policies and methods to ensure that documents are developed without bias or improper influence. The HRS policy on relationships with industry and other entities can be found in [Appendix C](#) of the Heart Rhythm Society Code of Ethics & Professionalism and in the HRS Scientific Documents Methodology Manual. [Appendix 1](#) is a comprehensive list of relationships with industry and other entities disclosed by the writing committee members.

Document review and approval

This statement was approved by the writing committee and underwent internal review by the HRS Scientific Documents Committee.

Document updates

The HRS Scientific Documents Committee reviews each scientific document for currency every 2–5 years after publication.

Document scope and rationale

The field of clinical cardiac EP has a rich history of clinician-driven innovation, marked by numerous examples where practicing clinicians either modified existing approaches or adopted new treatments based on their experience treating patients. In these cases, clinicians were motivated by the desire to improve outcomes in their patients, and through the combination of practical experience and rigorous design and execution of clinical trials, innovation proceeded into the era of modern cardiac EP.

Against this background, the landscape of innovation is shifting in EP with the integration of artificial intelligence (AI) and digital health technologies (DHT). These advancements bring challenges to clinical workflow integration driven by technology companies, policy initiatives, and regulatory frameworks, resulting in a transformation of health care. The vast electronic health record (EHR) combined with the sheer amount of digital data produced by wearable/implantable monitors offers a critical opportunity to use AI/DHT in health care, and in particular in clinical EP, to improve management, analysis, organization, and clinical workflows.^{1,2} Governments and professional organizations are already enacting national and international strategies for AI research, deployment, and oversight, reflecting a top-down approach

to integration. For clinical EP, this creates a dual challenge: to uphold its tradition of clinician-led problem-solving while simultaneously navigating new and rapidly evolving technologies.

In this statement, we address the process of AI/DHT integration in clinical EP workflows. Using a conceptual framework rooted in the health-care delivery cycle (Figure 1), we explore (1) current and emerging applications, (2) decisions around adoption and implementation, and (3) the evaluation of safety and efficacy after deployment. By doing so, we highlight the tension and the synergy between the EP tradition of clinician-driven innovation and the growing influence of top-down technology integration, recognizing that sustainable progress will require both.

Applications

The potential applications of AI/DHT in EP are vast, spanning automation, organization, and clinical prediction. Conceptually, these functions align with the health-care delivery cycle:

- Automation streamlines routine, repetitive tasks.

- Organization enhances the processing and structuring of large, complex datasets.
- Prediction offers capabilities beyond human performance, such as disease detection and evolution, and risk stratification.

Automation

Automation using AI/DHT in clinical EP workflows aims to streamline routine tasks traditionally performed by clinicians or specialized personnel to enhance accuracy, efficiency, and consistency, allowing clinical staff to focus more on complex clinical decision-making and direct patient care.

A significant area in EP benefiting from AI automation is interpretation of time-voltage series data, such as interpretation of the electrocardiogram (ECG). Manual 12-lead ECG or ECG-patch monitor interpretation is labor-intensive and susceptible to human variability.³ Advanced AI algorithms have shown high accuracy³ in automatically identifying arrhythmias such as atrial fibrillation,^{4,5} ventricular tachycardia,⁶ and heart block.⁷ Modern AI-driven ECG systems utilize

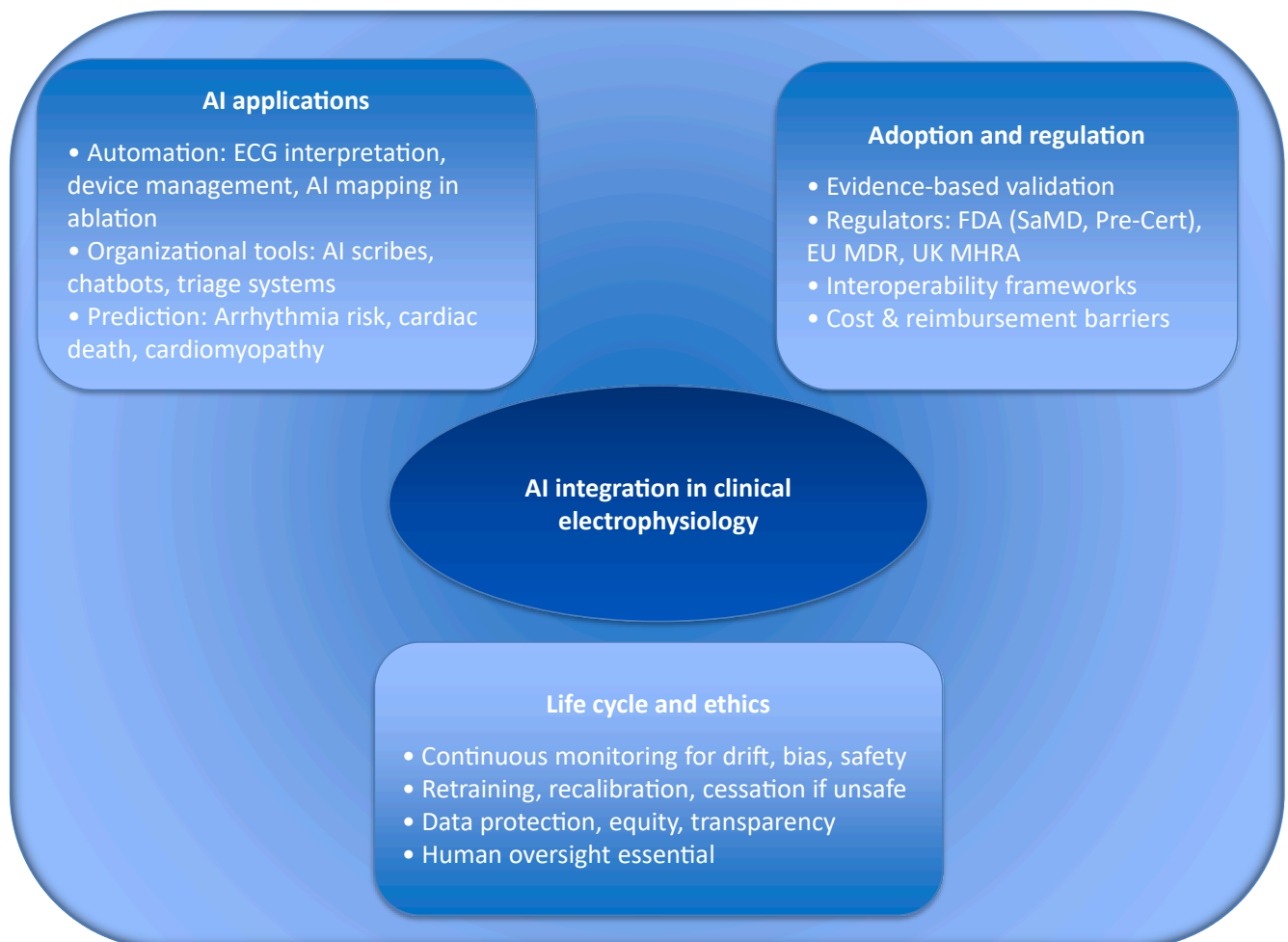


Figure 1

Adoption, regulation, ethics, and life cycle monitoring of AI algorithms in clinical electrophysiology. AI = artificial intelligence; EU MDR = European Union Medical Device Regulation; FDA = Food and Drug Administration; Pre-Cert = Software Precertification; SaMD = Software as a Medical Device; UK MHRA = United Kingdom Medicines and Healthcare products Regulatory Agency.

sophisticated deep learning models trained on extensive datasets, achieving diagnostic accuracy comparable or superior to that of expert cardiologists.^{8,9} Automating actionable ECG interpretation not only accelerates diagnosis but also may enable rapid and accurate clinical intervention, only when needed, which is particularly beneficial in emergency and ambulatory care settings.

Within the cardiac implantable electronic device realm, automation has evolved toward closed-loop systems,¹⁰ including implantable cardiac monitors, pacemakers, and implantable cardioverter-defibrillators. AI algorithms continuously analyze patient-specific cardiac parameters, enabling dynamic adjustment of device settings like pacing rates or sensing thresholds. Such automation is expected to optimize therapeutic effectiveness and patient comfort without frequent clinician intervention, reflecting a significant advancement in personalized patient care.¹¹

Interpreting ambulatory monitoring data from wearable and implantable cardiac devices represents another significant application of automation in diagnostic and preventive cardiac EP care. Continuous remote-monitoring produces substantial data volumes that often burden clinical teams. AI-driven analytical tools automatically screen and prioritize this data, highlighting abnormal findings that require clinician review. Such automation may significantly reduce clinical workload, increase detection rates of clinically significant arrhythmias, and facilitate prompt clinical response.^{12,13}

Automation may also significantly affect the EP procedural environments. During ablation procedures, advanced mapping systems now incorporate machine learning (ML) algorithms to assist electrophysiologists in interpreting complex signals and electroanatomic activation maps.^{14,15} AI-enhanced mapping software rapidly integrates electroanatomic data,¹⁶ automatically identifying critical arrhythmogenic substrates such as slow conduction areas or scar tissues.¹⁷ This automated guidance is essential for accurately targeting interventions in procedures like atrial fibrillation and ventricular tachycardia ablation. Recent validation studies indicate these AI-enhanced mapping systems significantly reduce procedural times and recurrence rates, improving overall procedural outcomes.¹⁸

Finally, in the outpatient EP practice environment, AI models including large language models (LLMs) may help clinicians address a variety of diagnostic and prognostic questions and may create a more natural interface for both patients and clinicians to interact with data.^{19–21} However, the field is still relatively nascent.²² AI-driven automation in EP exemplifies integrating advanced technology within clinical workflows to improve precision, efficiency, and patient outcomes.

Organizational tools

Organizational efficiency is very important in EP practice, where large volumes of patient data, including remote-monitoring data, must be captured, structured, interpreted, and communicated. AI/DHT-driven tools are increasingly being adopted to streamline these workflows both in EP clinics

and across health-care systems in general, with the goal to enhance value-based care and reduce the administrative burden on clinicians.

Assistive AI tools are increasingly being adopted to automate routine data management tasks. One example is the use of LLM-powered systems to transcribe raw audio recordings from clinician-patient encounters and generate structured draft clinical notes. These tools, often referred to as ambient AI scribes, have demonstrated reduction in documentation time and improved workflow efficiency.²³ Several health systems have adopted these tools into routine practice, particularly in high-volume outpatient settings. In parallel, AI-powered chatbots are being implemented to manage patient communications through EHR. These chatbots can automatically draft responses to common patient inquiries, ranging from medication refills to test result explanations, before routing them to clinicians for review and approval, resulting in reduction in physician task load and burnout, although reduction in charting time was not observed.²⁴

As LLMs become embedded in clinical workflows, prompt engineering, defined as the ability to frame clear, well-structured, and context-rich queries to LLMs, will increasingly be a necessary skill for clinicians alongside traditional digital literacy. Building basic prompt engineering competencies into EP training and continuing education can help ensure that AI-assisted documentation, decision support, and patient communication are used safely, efficiently, and in ways that reflect clinical intent.

Augmentative AI/DHT tools can further enhance organizational efficacy and value-based care delivery through clinician decision support and disease monitoring. These systems can provide insights by identifying patterns and generating actionable insights from EHR-derived data.^{25,26} In addition, remote patient monitoring is well established in the management of patients with cardiac electronic implantable devices. Data from these implanted devices, including arrhythmias and device parameters, is routinely monitored and transmitted to clinical care teams, generating large volumes of data. To support interpretation of these high-volume data, many device clinics use third-party platforms that apply AI-driven triage algorithms, using color-coded acuity indicators. However, despite these tools, a substantial proportion of transmissions and alerts contain non-actionable data.²⁷ Advanced AI-based analytics of raw signals from devices to determine which alerts are truly actionable may significantly reduce clinic workload.²⁸

Finally, consumer-facing wearable and non-wearable smart devices are being increasingly adopted by patients with data that are now frequently shared with clinicians. AI tools could triage these data transmissions; however, because of the lack of interoperability across various device manufacturers and EHR systems, the development and training of AI models for processing these heterogeneous data remain limited.²⁹ Although there are advances made in this area in select health-care systems,³⁰ addressing these interoperability challenges and leveraging AI/DHT for data processing will be important to enable streamlined

management of patient-generated data without increasing clinician workload.^{31,32}

Risk prediction and disease detection

The use of data to guide decisions in detecting prevalent disease or predicting future incident disease has increased dramatically under the umbrella of evidence-based medicine.³³ In many ways, this trend has culminated in the desire to integrate the sophisticated methodology of AI/DHT to produce quantitative estimates for entities that would not necessarily be apparent to the treating (human) clinician and thus produce “supra-human” capability.^{34,35}

The semantics of defining such an application as supra-human are not trivial; what seems impossible to the untrained eye can be rote to the expert, rendering a task that would be supra-human to one individual simple automation to another: a non-EP developer might infer that a deep learning model trained to identify the optimal site of ablation for ventricular tachycardia³⁶ is producing supra-human functionality, whereas an experienced electrophysiologist might infer that the model is merely identifying standard locations for ventricular tachycardia ablation. Nonetheless, the number of AI/DHT applications that use data to make predictions grows by the day, creating a challenge to the busy clinician who must determine whether to act on the information.

Following the general rule of data science that more can be done with larger amounts of information, AI/DHT models for risk prediction or disease detection have primarily been centered on applications where data are abundant. Predicting future AF,^{4,37,38} identifying prevalent cardiomyopathy,^{39,40} or predicting risk of sudden cardiac death⁴¹ from a 12-lead ECG are examples, where the standardization of the ECG tracing and the sheer number of centers with large ECG databases have provided a critical opportunity to expand the information provided by a tracing and guide programs for targeted screening or risk mitigation.

Prediction using EHR data is another emerging area where large amounts of information on millions of real-world patients can be leveraged itself⁴² or combined with imaging data,⁴³ ECG/telemetry data,³⁸ or genetic information.⁴⁴ The expansion and standardization of EHRs worldwide, and efforts in data harmonization⁴⁵ to ensure that a lab value in one system can be mapped to that of another, will only increase the number of prediction models that emerge.

Readiness for adoption and implementation

Deciding when to adopt and use AI/DHT

The decision of whether to adopt and implement an AI/DHT depends on its role in the care workflow, the level of risk it is associated with, and whether the specific task is either presently performed by a human (completely or incompletely) or extends the capability of most human clinicians. Closed-loop and semi-autonomous AI/DHT systems that can directly alter therapy or device parameters, even with rigorous monitoring, warrant enhanced regulatory scrutiny because of their immediate potential effect on patient safety. In this context,

EP-focused AI that can trigger or modify interventions (eg, device reprogramming, automated dosing, or ablation guidance) should be treated as higher risk and subject to stricter pre-market evaluation and post-market surveillance than purely advisory decision-support tools. The process of making this decision can be guided by several resources, including scientific literature, regulatory bodies, and internal needs assessment, with attention to technical demands and cost. In this section, we delve into these various resources and considerations that must be addressed prior to adoption. Illustrative clinical EP workflows are presented in the Supplemental material.

Literature and scientific validation

Today, AI/DHT tools for arrhythmia detection, risk prediction, and ablation planning are emerging from both academia⁴⁶ and industry.¹⁴ When integrating AI/DHT into clinical EP workflows, clinicians must assess the scientific evidence⁴⁷ to assess feasibility, safety, and efficacy.

Professional societies stress that scientific validation should ideally precede adoption.⁴⁷ A recent HRS and American Heart Association scientific statement noted that few AI tools have demonstrated improved outcomes sufficient for routine use.¹ When AI directly influences diagnosis or therapy, such as guiding ablation or detecting arrhythmias, clinicians should look for published evidence or expert consensus confirming its safety and effectiveness.³⁴ For low-risk or assistive tools, formal publication may not be essential initially but should still be used with oversight and data collection to inform future use.

One recent example of an AI system that underwent formal clinical evaluation was the TAILORED-AF trial, a multicenter randomized controlled trial demonstrating that an AI-guided ablation strategy based on spatio-temporal dispersion improved arrhythmia-free survival in patients with persistent and long-standing persistent atrial fibrillation.¹⁴ This example supports using standard approaches for evaluation of AI/DHT similar to those used for evaluation of a new medication or medical device.³⁴ The importance of this approach was identified in a few notable examples, such as in ablation planning models, where an AI/DHT that outperformed traditional risk scores gained traction only after prospective validation,⁴⁸ and in an evaluation of an AI-based arrhythmia detection algorithm for insertable cardiac monitors that required formal evaluation to demonstrate safety and accuracy.⁴⁹ Broadly, it is anticipated that despite the sophisticated technology and innovation behind the design of many AI/DHT products, integration should be based largely on the well-established process of clinical trial evaluation.

For practicing EP clinicians and health systems, although AI/DHT should be used “as labeled,”³⁴ a practical “validation checklist” may be more useful than abstract performance indicators. At a minimum, vendors should be able to describe (1) the underlying datasets, including, eg, device types, rhythm distributions, inpatient vs outpatient recordings, labeling procedures, and handling of poor-quality or ambiguous signals; (2) internal validation methods, such as cross-

validation or bootstrapping, and the associated estimates of discrimination (eg, sensitivity, specificity, positive and negative predictive values, and area under the receiver operating characteristic curve) across clinically relevant thresholds; (3) external validation in independent sites that differ in geography, patient demographics, and hardware vendors, with transparent reporting of performance in key subgroups (sex, race and ethnicity, age, comorbidities, and device type); (4) assessment of calibration and failure modes, including false-alarm rates expressed in interpretable units (eg, false alerts per 100 transmissions or per patient-month); and (5) prospective evaluation, ideally starting with a silent phase followed, for high-stakes use, by randomized or pragmatic trials, showing effects on process measures and patient outcomes. Documented procedures for ongoing performance monitoring, version control, and revalidation after major model updates are equally important and should be viewed as part of the scientific evidence base rather than solely as technical details.

Formal regulatory process

Regulatory bodies, such as the US Food and Drug Administration (FDA), play a critical role in evaluating and approving medical devices, including software-based technologies that meet the definition of a "device." The International Medical Device Regulators Forum (IMDRF) defines Software as a Medical Device (SaMD) as software intended to be used for ≥ 1 medical purposes without being part of medical device hardware.⁵⁰ The FDA has developed policies that are tailored for SaMD to safeguard the safety and effectiveness of this technology as it pertains to patients and health-care professionals.⁵¹ Subsequently, for software-specific changes in the design that have been reviewed and cleared under a 510(k) notification, the FDA's Center for Devices and Radiological Health has published a guidance document⁵² that includes a risk-based approach to help determine when a premarket submission is required.⁵³

The FDA's approach to AI/DHT has evolved considerably. Key policies include the digital health Software Precertifica-

tion (Pre-Cert) program and comprehensive guidance on device software functions and mobile medical applications.⁵³ The FDA's Pre-Cert program is best understood as a completed pilot rather than an active regulatory pathway; it was launched in 2017, formally concluded in 2022 with the publication of a final report, and is not currently available as a standalone mechanism for market authorization.⁵³ At present, AI/DHT-enabled devices continue to be reviewed through established pathways, including premarket notification (510[k]), de novo classification, and premarket approval, with concepts from the Pre-Cert pilot serving primarily as a model for potential future policy reforms that would require additional statutory authority. These frameworks aim to provide clarity on what constitutes a regulated medical device versus a general wellness product and on the level of regulatory scrutiny that is required. Also, the FDA's digital ambulatory health initiatives focus on ensuring the quality and reliability of technologies used in outpatient and remote care settings, acknowledging the shift from traditional clinical environments to the use of these technologies.

For the practicing clinician, although it is paramount to understand the regulatory processes to ensure patient safety and effective adoption, it remains a daunting task. Clinicians should expect that any AI/DHT they consider adopting for diagnostic, treatment, or risk stratification⁴⁶ purposes has been approved by a relevant regulatory body for that specific indication. Using such technologies for off-label uses (ie, for purposes not reviewed or cleared by the FDA) introduces both clinical and legal risks, as the safety and efficacy for that specific application have not been established and clinicians may not be aware of the vulnerabilities and uncertainty inherent in a given AI/DHT that also have to be communicated and consented to by the patient. To avoid potential undesired outcomes, it is recommended that algorithms be used as labeled by the FDA with respect to the patient cohort that have been evaluated.^{34,54}

Since the primary objective of adopting AI/DHT-based medical technologies in clinical settings requires incorporating data streams from such devices, it is critical to define

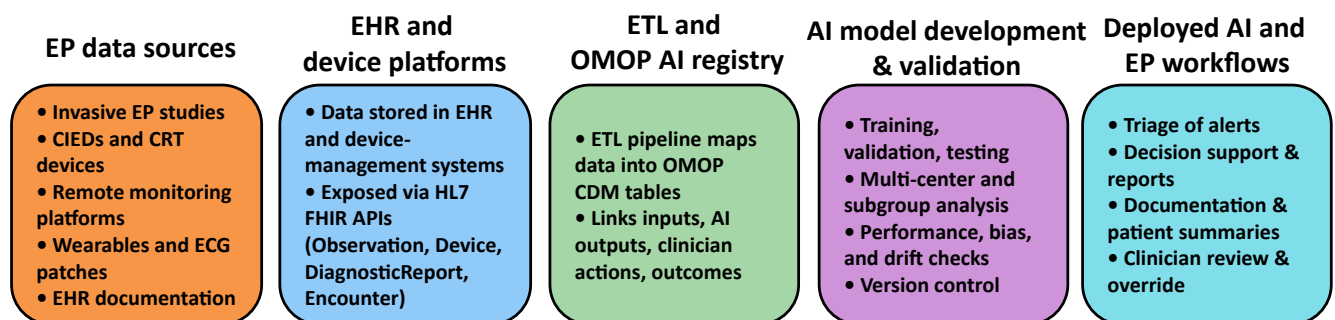


Figure 2

Data pipeline for interoperable AI in clinical electrophysiology and a learning health system. Data pipeline linking electrophysiology (EP) data sources, electronic health record (EHR) and Fast Healthcare Interoperability Resources (FHIR), Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), and artificial intelligence (AI) tools, enabling learning loops and traceability in EP workflows. Primary operational data flow: EP data sources → EHR/FHIR layer → OMOP AI registry → AI development and validation → deployed AI in EP workflows. AI = artificial intelligence; API = application programming interface; CIED = cardiac implantable electronic device; CRT = cardiac resynchronization therapy; ECG = electrocardiogram; ETL = extract, transform, load; HL7 = Health Level 7.

the clinical needs, priorities, and requirements toward medical device interoperability (Figure 2), which is essential for integrated care and preventing data silos.^{31,32} In these situations, clinical use cases with precise descriptions of workflows, and human-device and device-device interactions, are expected to drive the development of robust interoperable procedures. These aims can be achieved by establishing precise processes with respect to which data and functionalities of a medical device can safely enhance health-care outcomes and can therefore be shared across stakeholders comprising the health care system. These processes should include an architectural framework describing the interactions between components of the health care system and a robust and transparent process for capturing and defining device vocabularies and communication protocols.^{31,32}

Internationally, regulatory standards for AI/DHT have notable differences. Although the FDA has pioneered many frameworks, other regions like the European Union (EU) with its Medical Device Regulation and In Vitro Diagnostic Regulation, or the UK's Medicines and Health-care products Regulatory Agency (MHRA), operate under distinct legal and regulatory paradigms. These differences can manifest in varying approval pathways, data privacy requirements (eg, general data protection regulation in the EU), and post-market surveillance expectations. Clinicians engaged in global health or those considering technologies developed abroad must be aware of these disparities before using them in a new location.

Emerging guidance for adaptive AI/ML-based SaMD

In addition to high-level SaMD frameworks from IMDRF, regulators have begun to publish AI-specific guidance focused on adaptive or learning software. In the United States, the FDA, together with Health Canada and the United Kingdom's MHRA, has articulated 10 Good Machine Learning Practice guiding principles for ML-enabled medical devices, emphasizing representative data, robust engineering, human-AI interaction, and life cycle monitoring.⁵⁵ More recently, the FDA has issued guidance on predetermined change control plans for AI-enabled device software functions. These predetermined-change control plans, reviewed as part of the marketing submission, describe the scope of future model changes, the methods used to develop, validate, and implement them, and the manufacturer's assessment of their impact, allowing certain updates to be made without repeated full submissions while maintaining a reasonable assurance of safety and effectiveness.⁵⁶ For EP-focused AI and digital health technologies, these tools provide a practical blueprint for managing algorithm retraining (eg, to incorporate new device data or populations) under a controlled, regulator-reviewed plan. In Table 1, we present regulatory approaches to adaptive AI/ML-based SaMD under the FDA, the EU Medical Device Regulation/Artificial Intelligence Act, and the United Kingdom MHRA. Together, these developments signal a shift from purely static SaMD regulation toward explicit frameworks for learning health

system-oriented AI, in which model evolution is anticipated, specified, and governed rather than treated as an exception.

Initial workflow and added value assessment

Integrating AI and DHT into the clinical EP practice requires a structured approach to evaluating current workflows and identifying opportunities for improvement. Several conceptual frameworks can support this process, ensuring that AI initiatives are purposeful, feasible, and aligned with clinical goals and health care-system priorities.

Heilmeier Catechism, developed at the Defense Advanced Research Projects Agency (DARPA), guides early planning by posing essential questions: What problem are we solving? How is it addressed today? What is new? What are the risks?⁵⁷ In EP, this model helps clarify whether AI/DHT meaningfully improve detection of arrhythmias, reduces workload, or enhances outcomes compared with existing ECG interpretations and device monitoring, among other applications. User-centered design offers a mature body of methods, such as needs assessment, participatory co-design, rapid prototyping, and usability testing, to ensure that AI/DHT align with clinician and patient workflows rather than imposing new burdens. Complementarily, implementation science frameworks (eg, the Consolidated Framework for Implementation Research and RE-AIM [Reach, Effectiveness, Adoption, Implementation, and Maintenance]) provide structured approaches for adapting interventions to local context and evaluating adoption, fidelity, and sustainability when integrating AI/DHT into EP services. The 5 rights of Clinical Decision Support emphasize delivering the right information to the right person, in the right format, through the right channel, at the right time.⁵⁸ For example, an AI ECG algorithm predicting AF should integrate seamlessly and in real time into the ECG review workflow at a point in the care process where meaningful action can be taken by clinicians (ie, enhanced surveillance). This requisite is in contrast to many current algorithms, which are run post hoc, returning risk alerts that can be overlooked, dismissed, or outdated. This alignment reduces the likelihood of alert fatigue and promotes trust in the AI model and the notification system.

Frameworks from implementation science, such as RE-AIM and PRISM (Practical, Robust Implementation and Sustainability Model), provide additional guidance.^{59,60} RE-AIM focuses on both effectiveness and real-world uptake, encouraging implementers to track how many patients benefit, whether clinicians adopt the system, and whether results are maintained over time. In EP, this means not only assessing AI performance metrics but also monitoring unintended consequences, such as overdiagnosis of low-risk patients. Using the aforementioned frameworks and monitoring the performance of the AI/DHT throughout their life cycle ensures that these technologies are assessed not only for accuracy but also for their broader operational and clinical impact. Such a deliberate, structured approach maximizes the chance that AI/DHT will improve care while minimizing unintended burdens.

Table 1 Regulatory approaches to adaptive AI/ML-based software as a medical device

Regulatory Aspect	United States – FDA	European Union – MDR + AI Act	United Kingdom – MHRA
Primary legal basis for AI/ML-based SaMD	Software as a medical device is regulated under existing device pathways (510 (k), De Novo, premarket approval) within the Federal Food, Drug, and Cosmetic Act.	MDR and the In Vitro Diagnostic Medical Devices Regulation (EU 2017/746) govern medical devices (including AI software), whereas the AI Act adds AI-specific obligations for “high-risk” systems, which include most AI-enabled medical devices.	UK Medical Devices Regulations, supported by the “Software and AI as a Medical Device (SaMD/AiMD) Change Programme” policy roadmap.
Guidance on adaptive AI	GMLP principles plus guidance on PCCPs for AI-enabled software functions.	The AI Act requires risk management, data governance, transparency, human oversight, and post-market monitoring; detailed rules for adaptive AI are being developed via harmonized standards.	The Change Programme explicitly targets software and AI across the life cycle and aims to align with GMLP-type principles and emerging international practice on adaptive AI.
AI risk-management standards	Builds on ISO 14971 and IEC 62304; PCCPs and GMLP emphasize AI-specific risks such as bias, drift, robustness, and human-AI interaction.	MDR relies on ISO 14971; the AI Act is expected to draw on AI-specific frameworks (eg, ISO/IEC 23894, NIST AI Risk Management Framework) for high-risk systems.	Aligns with ISO 14971 and IEC 62304, and indicates use of AI-specific risk-management concepts as part of the Change Programme and international standardization efforts.
Mechanism for managing post-market AI/ML changes	PCCP submitted with the original application defines allowed model changes, validation methods, and monitoring, enabling certain updates without a new full submission.	MDR change rules apply to device modifications; the AI Act adds continuous risk management and post-market monitoring, with PCCP-like mechanisms still emerging.	The roadmap anticipates clearer pre- and post-market expectations for AI changes and potential convergence on PCCP-style models for adaptive software.
Implications for EP AI and digital health	EP AI tools (eg, arrhythmia detection, device-alert triage) should be designed under GMLP, with PCCPs for planned retraining and robust real-world performance monitoring.	EP AI will typically be classified as high-risk, requiring integrated MDR and AI Act conformity assessment, strong risk controls, and structured post-market surveillance.	EP AI developers must plan for evolving UK requirements, ensuring that adaptability and learning are explicitly addressed in submissions and change-control strategies.

AI = artificial intelligence; EP = electrophysiology; GMLP = Good Machine Learning Practice; IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; MDR = Medical Device Regulation; MHRA = Medicines and Healthcare products Regulatory Agency; ML = machine learning; NIST = National Institute of Standards and Technology; PCCP = predetermined-change control plans; UK = United Kingdom.

Cost reduction and efficiency improvements are major drivers of AI/DHT adoption. For example, algorithms that autonomously interpret ECGs or automate premature ventricular contraction burden quantification on a Holter monitor can shorten diagnostic workflows and reduce labor costs.⁶¹ However, poorly tuned systems can overwhelm clinicians with excessive low-priority notifications, negating efficiency gains and increasing cognitive burden.

Clinical outcomes are a key dimension of added value beyond practical benefit in cost and care efficiency. Deep learning models have shown superior sensitivity for arrhythmia detection compared with rule-based methods.⁶² Nonetheless, higher sensitivity can also produce more false positives, requiring careful calibration to avoid unnecessary diagnostic testing and other interventions in asymptomatic or unaffected patients. AI models deployed in clinical environments can be subject to continuous monitoring and improvement through the establishment of learning systems that link algorithm outputs with clinical outcomes in a

scalable manner, for example, via natural language processing methods applied in the EHR.

Finally, clinician and patient satisfaction are critical to sustainability of AI-based models of EP care. Tools that save time and present clear, interpretable results are more likely to be embraced.

Technology requirements

AI/DHT introduce unique technological considerations that health care systems and clinics may or may not be equipped to manage without sufficient support services. For example, an AI/DHT may need to store data outside the current EHR or transmit data from external locations back to the clinical care environment. These requirements might extend beyond the support capabilities of vendors or introduce a new technology burden for support teams of health care systems, resulting in privacy/security vulnerabilities and liability issues.

In addition, requirements with respect to the computational infrastructure must be considered, as this is critical to

optimize training and workflow. Cloud computing allows for on-demand service, broad network access, rapid elasticity, and measured services.⁶³ However, data privacy and confidentiality remain a significant concern, especially when data and models span institutions and countries.^{64–69} The FDA clearly defines HIPAA guidelines for protecting patient privacy, but international privacy policies can vary, adding complexity or potentially compromising capability of an AI/DHT that requires specific personal information to function. Furthermore, reliability and transparency of data handling by third parties with lack of experience is concerning,⁷⁰ particularly in the health-care domain where data compromise can cause direct and potentially irreparable harm to health care systems and individuals. Although health care systems are increasingly aware of the cybersecurity issues pertaining to the protection of their EHRs, the same cannot be assumed for a start-up technology company. Broadly, these issues support the need for early engagement with data security experts prior to adoption of any new AI/DHT to prevent unwanted compromise in privacy, security, and ultimately reputation for clinicians and health care systems.

Each prediction or recommendation should be linked to auditable identifiers, enabling clinicians to retrieve the underlying signals and context, from within the EHR or device-management system. When possible, models should be designed and tested to function across multiple hardware vendors, with clear mapping between lead configurations and signal labels. Bidirectional, well-documented APIs (short for application programming interfaces) are needed so that AI outputs can be written back into the EHR, remote-monitoring dashboards, and EP lab systems in structured form rather than as static PDF reports. Health system contracts should spell out how data will be shared between institutions and vendors, how long data and model outputs will be retained for audit and quality-improvement purposes, and which party is responsible for maintaining compatibility as systems evolve. Such concrete requirements make interoperability assessable at the time of procurement and help ensure that AI/DHT solutions strengthen, rather than fragment, EP workflows.

Costs and reimbursement for vendors and health systems

For AI/DHT with scientific validation and regulatory approval that are deemed appropriate for integration into a health care system, cost is still an important barrier to implementation and widespread use. At present, there is no single, stable reimbursement mechanism dedicated to EP-focused AI/DHT; instead, coverage is distributed across several evolving code families. In the United States, the Centers for Medicare & Medicaid Services (CMS) and the American Medical Association (AMA) have introduced remote therapeutic monitoring codes 98975–98981, which reimburse for initial setup and patient education, device supply, and treatment management time for remote monitoring of therapy adherence and response. These codes are currently oriented toward respiratory, musculoskeletal, and cognitive-behavioral

indications rather than cardiovascular care, but they provide a conceptual template that could, in principle, be extended to digital therapeutics for arrhythmia management or heart failure self-management if CMS and AMA were to broaden their scope.⁷¹

For now, many cardiovascular AI solutions rely on category III Current Procedural Terminology (CPT) codes that track use of novel algorithms but do not guarantee payment. Recent examples include CPT codes 0764T and 0765T, which describe computerized ECG analysis with AI for detection of cardiac disease or risk-based assessment of cardiac dysfunction, for which CMS has begun to establish national payment rates for AI-enabled ECG tools, such as hypertrophic cardiomyopathy. Additional category III codes 0992T and 0993T have been approved for noninvasive assessment of cardiac risk based on AI-enabled perivascular fat analysis from coronary computed tomography, reflecting parallel innovation in imaging-based cardiovascular risk stratification. Furthermore, category III codes have been issued for AI-enabled cardiac auscultation platforms that combine digital stethoscopes with structural murmur, low ejection fraction, and arrhythmia detection algorithms. Together, these examples underscore that reimbursement for cardiovascular AI is advancing but remains fragmented, reinforcing the need for EP clinicians and health systems to track code-specific coverage decisions and to advocate for more coherent, indication-appropriate payment models.

Therefore, AI/DHT they must be either (1) developed and disseminated within the health care system thereby offsetting the costs of purchasing new tools, or (2) tied to system-wide increases in revenue or decreases in cost, typically over a relatively short time horizon. For health care systems without the expertise or resources to develop their own AI/DHT, costs are most likely to be defrayed by increasing payer reimbursement (such as with higher throughput of testing or procedures), improving clinician efficiency to expand capacity for care, or directly reducing costs (eg, avoiding rehospitalizations or reducing hospital-associated infections).

However, such a system inherently inhibits the integration of AI/DHT, as the motivation for their use would typically arise from clinicians who must evaluate them, model the potential cost savings, and obtain administrative buy-in for the up-front costs. For developers of AI/DHT, providing clinicians with clear evidence on how their integration can offset health-care costs can have a profound effect on their integration. Other approaches to promote integration could include cost-free pilots provided by companies, public loan programs for health care systems seeking to improve efficiency in care, or institutional grant programs integrated under the health care-system leadership (ie, informatics and medical leadership) to promote innovation in clinical practice, although these small-scale approaches might limit broader adoption. At a health care-system level, having clearly defined roles in the implementation and continuous monitoring and evaluation of AI/DHT can facilitate more timely review, implementation, and assessment of AI/DHT.

Efficacy and safety throughout the life cycle

Deciding when to adopt and use an AI/DHT

SaMD is somewhat unique in that it can be continuously modified and improved through use (part of the standard software development life cycle). Therefore, clinicians adopting SaMD-based AI/DHT should also consider a product's continued evaluation throughout its life cycle, a process that includes ongoing assessment of clinical validity, data protection and safety, and the potential need to refine or cease use if standards are not met.

Systems of data collection

Throughout the AI/DHT adoption and maintenance process, health care systems must establish key performance indications and methods to collect data and assess the added value, and potential unintended consequences, that result from their adoption.⁷² The collected data should provide real-world feedback to the health care system with respect to whether the model meets ≥ 1 of the quintuple aims of a learning health system: (1) improving patient health, (2) reducing costs, (3) enhancing the patient care experience, (4) reducing clinician burnout, and (5) advancing health equity.⁷³ Unfortunately, compared with model development, there is limited guidance regarding the AI/DHT impact assessment and implementation in daily practice.⁷⁴ This challenge has likely contributed to the slow uptake of AI/DHT beyond ambient note-taking, for which there is very proximal feedback on model performance.⁷⁵

Therefore, establishing local governance enables the process of collecting the required data to validate an AI/DHT.⁷⁶ This governance structure should include clinicians who intend to deploy the AI/DHT, clinical informaticists, data scientists, operational leadership, and information technology personnel responsible for EHR or interfaces that connect systems outside of the EHR. A new AI/DHT outcome (eg, reduced time to chart closure, increased yield of atrial fibrillation monitoring, or improved procedural outcomes) has to be defined, and a process has to be established on how that outcome will be measured within the local health care system, establishing a silent trial with clearly defined benchmarks for success.⁷⁷ Additionally, the AI/DHT could be integrated in a non-production environment or made available to a limited number of users with the predefined data collected prospectively; such a process offers the opportunity to evaluate AI model outcomes locally for comparison with expectations, refine data collection methods for ongoing evaluation of the model, or perhaps retrain the AI model locally for performance optimization.

However, lack of a robust governance structure in health care systems runs the risk of furthering the digital divide.⁷⁸ Avoiding this situation will require prospective, multicenter implementation trials in diverse health systems (academic, private, public, rural, etc.) to enhance generalizability of AI/DHT deployment.

Easing continued local evaluation and validation may require technical enhancements. Along this vein, EHR

vendors are beginning to offer automated systems for data collection and validation (<https://github.com/epic-open-source/seismometer>). However, these solutions are often vendor-specific and may only be suitable for AI models incorporated into the EHR or developed by the EHR. Importantly, third-party platforms developed to provide vendor-neutral validation platforms require additional investment from health care systems. Finally, data collection should be adopted by the end user; if end users do not understand how to use an AI/DHT within their clinical workflow or do not trust a model, it is unlikely that it will be adopted or deliver its anticipated value. Mixed-method assessments that include usage metrics and qualitative techniques to assess adoption barriers and optimize clinical integration may ensure that the AI/DHT implementation fits into their clinical workflow⁷⁹ and can impact the expected outcomes.

AI/DHT evaluation process

After its approval for clinical use, post-market surveillance of AI algorithms is considered an important process aiming to ensure the effectiveness and safety of an AI algorithm throughout its life cycle. Once a data collection process is established and the technology is deployed in real-world clinical settings, continuous monitoring is essential to ensure that the AI algorithm function and outcomes remain as expected and patient safety is not compromised. This is a critical departure from traditional medical device regulation, as AI algorithm performance can change over time (known as performance drift). Post-market surveillance not only decreases the potential risks for patients but also benefits manufacturers by pinpointing key areas where product quality improvement may be required.³⁴ Formal quantitative assessment is particularly crucial for certain types of AI algorithms in health care, such as:

1. *Diagnostic AI.* Algorithms interpreting medical images (eg, radiology or pathology) or physiological signals (eg, ECGs) require continuous validation of their sensitivity, specificity, and predictive values against ground truth or human expert consensus.
2. *Prognostic and predictive AI.* Algorithms estimating disease progression, treatment response, or patient risk (eg, for sepsis, cardiac events, or readmission) must be regularly recalibrated and re-evaluated against actual patient outcomes to confirm their predictive accuracy over time.
3. *Treatment optimization AI.* Systems recommending drug dosages or therapeutic interventions need rigorous monitoring to ensure patient safety and efficacy, especially as patient populations or clinical guidelines evolve.

Given the dynamic evolution of AI/DHT, the FDA's role as a regulatory agency has evolved to serve as a collaborative partner to the industry through implementation of the Case for Quality program, through which the FDA is working with all involved stakeholders to improve the quality of medical products through a transformation of the emphasis to "focus on quality."⁸⁰ It consists of the following main components:

(1) focus on product quality, (2) data transparency enhancement, and (3) stakeholder engagement.⁸¹

Strategies to manage both expected and unexpected results from ongoing AI use are multifaceted. For predictable model degradation or shifts in data distribution, developers and health care systems should implement robust post-market monitoring pipelines that track key performance indicators, input data characteristics, and model outputs, including automated alerts for deviations outside predefined thresholds.

Another process that requires assessment involves the AI/DHT upgrades that may involve modification of its (1) performance without change to the intended use or new input type, (2) inputs without change to the intended use, or (3) intended use.³⁴ When performance issues are detected, several interventions are possible:

1. **Retraining.** The AI algorithm may need to be retrained on updated, representative datasets to account for new clinical realities or population shifts. This process must be controlled, validated, and potentially subject to further regulatory oversight, depending on the magnitude of the change.
2. **Recalibration.** Recalibration is less extensive than full retraining and involves adjusting model parameters to better align outputs with current clinical reality without fundamentally altering the model architecture.
3. **Cessation of use.** In severe cases where an AI model consistently demonstrates unacceptable performance, bias, or poses significant patient safety risks, its use must be immediately ceased. This requires clear protocols for identifying such scenarios and communicating findings to clinicians and regulatory bodies.

Finally, managing unexpected results often requires human oversight. Clinicians using AI/DHT must maintain a critical perspective and never cede ultimate decision-making authority to an AI algorithm. Integrating AI outputs within the broader clinical context, coupled with mechanisms for feedback and reporting anomalies to developers and regulators, forms a vital feedback loop for continuous improvement and safe adoption. Regulatory bodies are increasingly exploring “predetermined-change control plans” and frameworks to address the iterative nature of AI development, ensuring that necessary model updates can occur efficiently while maintaining regulatory oversight.

Conclusion

Although regulatory approval provides an initial stamp of safety and efficacy, the true test of AI/DHT lies in their ongoing performance in dynamic clinical environments. A vigilant post-deployment evaluation, coupled with responsive management strategies for model drift and bias, is indispensable for clinicians to harness the full potential of these technologies responsibly and safely.⁸²

The integration of AI holds immense promise for transforming medicine, yet to fully realize this potential it is imper-

ative to address the ethical challenges head on, according to the World Health Organization’s 2021 *Ethics and Governance of Artificial Intelligence for Health* guidance, which articulates 6 foundational principles for trustworthy AI in health care: autonomy, well-being, transparency, accountability, inclusiveness, and sustainability.⁸³ These principles complement broader human rights-based frameworks, underscoring that AI-enabled EP workflows must be designed and governed to protect patients while promoting equitable and sustainable health system benefit. The principles need to be implemented across country borders with robust data protection measures,⁸⁴ actively combating bias,⁸⁵ ensuring system transparency, and establishing clear accountability structures. By doing so, the clinical community can responsibly harness the power of AI/DHT to usher in a new era of efficiency, safety, and personalized patient care.³¹

As AI/DHT are adopted, evolve, and grow, human rights, such as the right to dignity, informed consent, privacy, and confidentiality, may be radically challenged or reconsidered. Yet, these ethical challenges must be adequately addressed if AI/DHT is to be widely adopted and used to improve medicine and human health, to preserve and enhance human autonomy and agency¹⁹ and to safeguard equitable access to these technologies. Furthermore, because of the global outreach of AI/DHT, its implementation requires an international framework to oversee its regulations and policies.³⁴

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Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hrthm.2020.04.013>.

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Peter A. Noseworthy, MD, FHRS	None	Optum	None	National Institutes of Health; National Institute on Aging; Agency for Healthcare Research and Quality; U.S. Food & Drug Administration; American Heart Association, Medtronic, inc.	None	None	None	AliveCor	None
Krishna Pundi, MD, FHRS	None	Evidently; iRhythm Technologies	None	American College of Cardiology; American Heart Association	None	None	None	None	None
Konstantinos C. Siontis, MD, FHRS (SDC Liaison)	None	Abbott Medical; AskBio; Bristol Myers Squibb; Johnson & Johnson; Novartis; Varian Medical Systems	None	Anumana; Novartis; Johnson & Johnson; Varian Medical Systems	None	None	None	Anumana	None

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Appendix 2 Reviewer disclosure of relationships with industry and other entities

Peer Reviewer	Employment	Honoraria/ speaking/ consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ partnership/ principal/ majority stockholder	Stock or stock options	Intellectual property/ royalties	Other
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Ajay Tripuraneni MD, FHRS	None	None	None	None	None	HelloAlfred	None	None	None

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