



# State of the Art of Artificial Intelligence in Clinical Electrophysiology in 2025: A Scientific Statement of the European Heart Rhythm Association (EHRA) of the ESC, the Heart Rhythm Society (HRS), and the ESC Working Group on E-Cardiology

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Received 7 March 2025; accepted after revision 22 March 2025; online publish-ahead-of-print 31 March 2025

#### **Aims**

Artificial intelligence (Al) has the potential to transform cardiac electrophysiology (EP), particularly in arrhythmia detection, procedural optimization, and patient outcome prediction. However, a standardized approach to reporting and understanding Al-related research in EP is lacking. This scientific statement aims to develop and apply a checklist for Al-related research reporting in EP to enhance transparency, reproducibility, and understandability in the field.

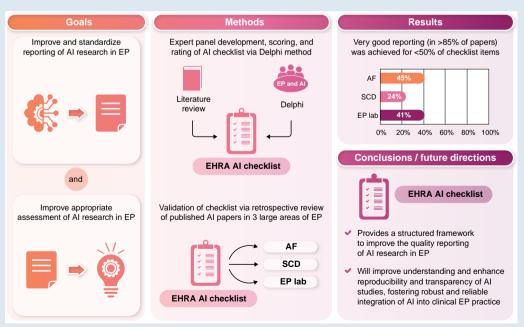
## Methods and results

An Al checklist specific to EP was developed with expert input from the writing group and voted on using a modified Delphi process, leading to the development of a 29-item checklist. The checklist was subsequently applied to assess reporting practices to identify areas where improvements could be made and provide an overview of the state of the art in Al-related EP research in three domains from May 2021 until May 2024: atrial fibrillation (AF) management, sudden cardiac death (SCD), and EP lab applications. The EHRA Al checklist was applied to 31 studies in AF management, 18 studies in SCD, and 6 studies in EP lab applications. Results differed between the different domains, but in no domain reporting of a specific item exceeded 55% of included papers. Key areas such as trial registration, participant details, data handling, and training performance were underreported (<20%). The checklist application highlighted areas where reporting practices could be improved to promote clearer, more comprehensive Al research in EP.

#### Conclusion

The EHRA AI checklist provides a structured framework for reporting AI research in EP. Its use can improve understanding but also enhance the reproducibility and transparency of AI studies, fostering more robust and reliable integration of AI into clinical EP practice.

#### **Graphical Abstract**



Al, Artificial Intelligence; EP, Electrophysiology; AF, Atrial Fibrillation; SCD, Sudden cardiac death

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## Introduction

Artificial intelligence (AI) is an emerging technology that holds great promise for the field of clinical electrophysiology (EP). This includes early detection of arrhythmias like atrial fibrillation (AF), personalized diagnosis and risk prediction for sudden cardiac death (SCD), procedural optimization and guidance for EP procedures. The integration of AI into clinical practice has the potential to improve personalized treatment strategies and improve patient outcomes.

Over the past decade, there has been a substantial increase in the number of publications reporting on the use of Al and machine learning (ML) in AF. $^{2-6}$  This is due to both the advancement in Al/ML techniques as well as the availability of open access databases, such as the PhysioNet repository and MIMIC-III which provide rich datasets for training and validating Al models in EP research. As research in this field continues to grow, there is increasing potential for Al to provide real-time decision support, enhance diagnostic accuracy, and streamline workflow in EP laboratories, paving the way for more efficient and effective patient care.  $^{8,9}$ 

While the recently released TRIPOD (Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis) +AI statement 10 aims to improve the quality, reproducibility, and clinical relevance of AI research in general, there is a pressing need for an AI-specific reporting framework tailored to EP, as the field presents unique challenges, such as integrating complex algorithms into clinical workflows, ensuring transparency in model development and validation, addressing data heterogeneity, and managing the potential for bias. To facilitate the application of AI to the field of arrhythmia and to enhance understanding, reviewing and reporting of AI studies in EP, a checklist is proposed. This checklist explains essential terms for a novice reader of AI, helps guide studies on clinically relevant questions, and provides scientists with a standardized approach to reporting and evaluating AI-related research.

We consequently developed an EHRA AI checklist tailored to EP and reviewed recent studies across three key areas: AF management, SCD,

and Al applications in the EP lab. By applying the checklist, we assessed reporting practices, identified areas for improvement, and summarized the current state of the art in these relevant topics. A glossary of terms in the field of Al in EP is shown in *Table 1*.

## Creation of the EHRA AI checklist

In alignment with the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) project, <sup>12</sup> and to enhance the quality of health research reporting in journal articles, several valuable manuscript checklists for reporting the evaluation of Al and ML models in medicine have been proposed (see Supplementary material online, *Table S1*). These documents provide guidance to authors and reviewers, helping to standardize and validate content in a more reproducible way, ultimately enhancing transparency and completeness in reporting.

In the field of cardiovascular (CV) medicine, only one specific document currently exists, which focuses on proposed requirements for evaluating ML in CV imaging. <sup>13</sup> More recently, other publications have highlighted the need for quality evaluation criteria in prediction models for CV diseases, also proposing initial solutions. <sup>14–16</sup>

## **Checklist development**

The members of the EHRA AI in EP Writing group were identified via nominations and recommendations from international professional CV EP societies, and first convened virtually to discuss and obtain consensus on aims and generating process of the scientific statement.

To define the items to be included into the dedicated checklist for group evaluation, a review of published literature proposing criteria or checklists relevant to Al, <sup>10,13,17–31</sup> as well as recent systematic reviews on the topic was performed. <sup>15,32,33</sup> The proposing team (E.S., D.D., E.G.C.) identified the potential items that could be relevant with a focus on the need for clinical EP experts and listed them as candidate reporting items, including variables, definitions, and rationale. This list was sent to the writing group for individual comment and refinement, thus resulting in the Al checklist that included 33 items (see Supplementary). The development process is outlined in Figure 1.

To encourage robustness and completeness in AI research reporting within clinical EP, the EHRA AI in EP writing group decided to utilize a modified prospective Delphi method based on the RAND/UCLA process.<sup>34</sup>

## Delphi process for consensus

In early 2024, the first round of virtual, electronic survey-based, individual Delphi voting was conducted, with no interaction amongst voting members. The survey included the initially selected 33 items, and for each of them, participants were asked to vote on each item using a 5-point Likert scale, as follows: 1 to 2: not relevant, should not be included; 3: may be appropriate to include 4–5: appropriate to include. In addition, for each item, a question asking the need for further refinement (i.e. in case of an unclear description) was also proposed, for which an open-ended response was possible.

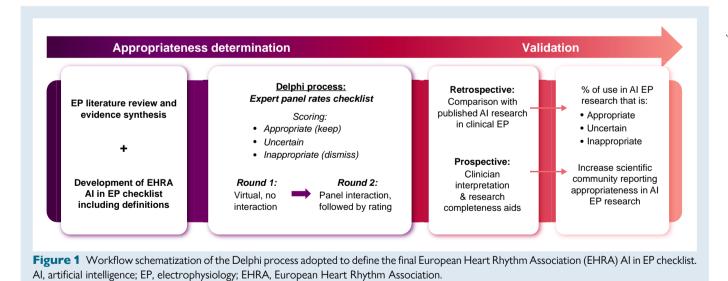
The working group reviewed responses for each checklist item, categorizing consensus levels based on the percentage of votes scoring 4 or 5. Consensus was defined as follows: weak for 50% to 75% agreement, moderate for 76% to 90%, strong for 91% to 99%, and unanimous for 100%. For items achieving a score of 1–2,  $\geq$ 75% consensus was needed to exclude the item from the checklist. From this first Delphi round, 82% responses were received.

In April 2024, a combined in-person and virtual meeting of the EHRA AI in EP writing group members was convened during the EHRA 2024

## Table 1 EHRA artificial intelligence in electrophysiology glossary

EHRA AI in EP glossary	
Artificial intelligence (AI)	A branch of computer science focused on creating algorithms with the aim of performing tasks usually requiring human intelligence, such as recognizing patterns, making decisions and predicting outcomes. Al can supersede human level intelligence in domain specific tasks
Open science in Al	The practice of promoting transparency, reproducibility, and accessibility in artificial intelligence research through open sharing of data, code, and methodologies to enhance collaboration and accelerate innovation in the field.
Machine learning (ML)	A subset of AI where algorithms learn patterns from data to make predictions or perform classifications (binary or multi-class) without explicit programming for each task. ML includes supervised learning, where specific labels are defined by the user, as well as unsupervised learning, which identifies patterns and structures in data without predefined labels. In EP, ML models are used to diagnose arrhythmias, predict outcomes, and optimize arrhythmia treatment.
Deep learning (DL)	A subset of ML that uses artificial neural networks to process and analyse information, where the features of interest are learned directly from the data, and not defined by the user.
Artificial neural network (ANN)	A foundational method in Al that teaches computers to process data in a way that is inspired by the human brain, using interconnected nodes or 'neurons' in a layered structure. It provides a means for dealing with complex pattern-oriented tasks, including classification, regression and pattern recognition. The nonparametric nature of ANN enables models to be developed without having any prior knowledge of the distribution of the data population or possible interaction effects between variables as required by commonly used parametric statistical methods.
Deep neural network (DNN)	A DNN is a neural network with multiple layers between the input and output layers required for high dimensional data analysis. DNNs encompass a variety of architectures designed for different tasks.
Convolutional neural network (CNN)	A specific type of DNN aiming to process spatial data using convolution layer and pooling layer, often used for image and signal analysis. In EP, CNNs can be applied to analyse ECG and imaging data to identify abnormalities.
Recurrent neural network (RNN)	A type of neural network designed for sequential data, such as time series and natural language. It retains memory of previous inputs to process sequences and produces outputs that depend on the entire input sequence.
Long short-term memory (LSTM)	A specialized type of RNN capable of learning long-term dependencies and patterns in sequential data, making it suitable for tasks requiring memory across many iterations.
Natural language processing (NLP)	NLP is a branch of AI that enables computers to process and interpret human language, both written and spoken. By combining computational linguistics with machine learning and deep learning, NLP can analyse unstructured data like clinical notes and electronic health records. In cardiology, it might help extract meaningful insights and identify patterns to potentially improve decision-making and patient outcomes.
Generative AI (GenAI)	A type of Al technology that uses algorithms and models, such as large language models (LLMs), to learn patterns from a dataset and then generate new data, including text, imagery, audio and synthetic data, that follows those patterns.
Transformer architecture	A neural network design at the basis of GenAl, especially effective for sequence data and NLP. By processing large volumes of text with the simple task of predicting the next word in every sentence, transformers give computers the power to understand language, learn facts, build abstract concepts about these facts.
Explainable AI (XAI)	Explainable AI is defined by a set of processes or methods for analysing or complementing AI models to make their internal logic and output transparent and interpretable, so that the underlying process could be better understood and meaningful by a human user, to increase trust towards AI.
Multimodal Al	Multimodal Al is based on the concept of multimodal models, where several unimodal neural networks are processing information available in different data types (i.e. text, images, audio, and video) in order to perform complex tasks.
Supervised learning	A category of ML that uses labeled datasets (i.e. with a label provided by a gold standard human interpretation) to learn the relationship between the input features and the output labels and train algorithms to predict outcomes and recognize patterns.

#### Table 1 Continued EHRA AI in EP glossary Unsupervised learning A type of ML that learns from unlabeled data (i.e. without the need for human supervision) and allows to discover potentially interesting patterns and insights without any explicit guidance or instruction making it useful for exploratory analysis. Digital twin A virtual representation of a patient, created by combining real-world data with computational models. In EP, a digital twin could simulate a heart's responses to ablation therapies or predict arrhythmia recurrence risk. 11 Internal validation The process of testing an Al model on data originating from the same source (i.e. hospital, equipment, patient group, ...) as the data with whom it was trained on, to evaluate performance. This is an initial step to ensure the model can generalize within a single dataset. The testing of an Al model on data originating from different sources (i.e. hospital, equipment, patient group, External validation ...) than those used in its training, thus ensuring the model's robustness and reliability across varied populations and settings. This is a critical step for wider clinical deployment. A metric used to evaluate the performance of a binary classification model. It measures the ability of a model to Area under the receiver operating characteristic curve (AUROC) distinguish between classes by calculating the area under the ROC curve, where a value of 1 indicates perfect discrimination and 0.5 indicates no better than random guessing. Area under the precision-recall curve A performance metric for evaluating binary classifiers, particularly in datasets with imbalanced class (AUPRC) distributions. It measures the trade-off between precision (positive predictive value) and recall (sensitivity), with higher values indicating better performance in identifying true positives while minimizing false positives. F1 score A harmonic mean of precision and recall, providing a single metric that balances the trade-off between the two. It is especially useful in evaluating classification models where there is an uneven class distribution. The F1 score ranges from 0 to 1, with higher values indicating better model performance. EHRA, European Heart Rhythm Association.



congress in Berlin, where results of the first round of Delphi voting were revealed, including a distribution of their ratings. Based on these results, 8 items did not exceed the predefined 75% threshold for being directly included. Ratings and checklist items were discussed to better understand those that had poor consensus and/or conflicting votes, also considering the received open-ended responses, to further refine those items by proposing amendments. No attempt was made to force the panel to consensus during this meeting.

After further adjustment of the 8 items according to the discussions, a second round of virtual, electronic survey-based, individual Delphi voting was conducted between 25 April 2024 and 2 May 2024, with no interaction amongst voting members. For this round, 77% of the authors responded, where 6 reformulated items reached consensus while two items were finally discarded, thus resulting in the final consensus on the EHRA AI checklist shown in *Table 2*.

**Table 2** The EHRA AI checklist (see Supplementary Interactive checklist). The table presents the final checklist, with the items that reached >75% consensus after the two rounds of the Delphi process

Item #	Category/section	Explanation	Rationale	Page no						
	TITLE									
i)	Title	Include clear terms to identify the study as using artificial intelligence, machine learning or other specific terms	To facilitate paper retrieval the terms artificial intelligence/machine learning/neural network in the context of EP should be used							
	INTRODUCTION									
1	Intended clinical use	Clearly describe the intended use and where in clinical workflow the model can be used and the objective of the study	To provide clear information of the clinical context in which to use the suggested AI solution in the context of EP							
2	Clinical benefit	Added benefit of Al compared with standard clinical care (gold standard)	To explain how the AI is performing compared with clinical care (gold standard/standard practice) to better evaluate the performance of the AI model and its potential added benefit							
	METHODS									
3	Data collection	Describe how data was collected	To provide a clear description of the dataset generation process, for example was data retrospectively of prospectively collected, from a single centre, or multicentre?							
4	Source (of data)	Describe the study design or source of input data and how it was acquired	To describe how the input data was acquired including the study design—for example RCT, cohort, registry data							
5	Development data set (model training data set)	Describe the data set	To describe the data set that was used for training of the model (i.e. 12-lead ECGs from a specific population)							
6	Participants	Describe the participants in the data sets, including eligibility criteria (inclusion and exclusion criteria).	Flow chart of participants (or table) suggested							
7	Comparator	Provide clear definition of how the gold standard was collected.  Clearly describe the gold standard and ground truth including limitations.	To describe in detail how ground truth the model was trained on was established—human interaction, consensus, review type). For example, how was the diagnosis of atrial fibrillation established (12 lead ECG interpreted by independent electrophysiologists)							
8	Testing data set	Describe the testing data set, in particular defining the data set split.	To describe in detail the data set that was used for testing the model, and the rationale bases on which the whole dataset was split and how.							
9	Sample size	Explain how the study size was arrived at.	For supervised models: Focus in particular on the training set including number of positives/negatives and the use of data augmentation/reduction (legitimization). For unsupervised models: focus on the number of participants							
10	Outcome	Clearly define standardized and reproducible outcome of clinical relevance.	To clearly describe the outcome, for example the accuracy of a specific algorithm							
11	Data type (source)	Clearly describe the data type for the study, including pre-processing	To describe the data used (i.e. ECG, image, EGM, omics, EHR) and its specification used to train and validate the model (i.e. was the information from an ECG in a image or a digital format)							
12	Data preparation	Input data handling, data augmentation and selection prior to analysis by the Al system, application of techniques to prevent data leakage.	To describe every step of handling the data (i.e. was the data reused at any time in the model, like using one ECG to provide several data points)							

Tabl	2	Continued

ltem #	Category/section	Explanation	Rationale	Page no						
13	Balanced groups	Clearly state how/if groups were balanced	To describe in detail the data set that was used for validating the model, and the rationale bases on which the whole dataset was split and how.							
14	Data issues (missingness / poor data / duplication / outliers)	Describe how handling of data of poor quality/ noise/missing data was performed	To provide information about possible issues in the utilized data, as well as how these were identified and handled. It should also be specified if there was a minimum standard for quality required for the input data, and where this standard was not achieved, how this was handled							
15	Feature engineering (extraction / selection / reduction)	If features are used, feature selection should be described including by whom features were extracted.	To describe the process of feature selection (i.e. handcrafted or automatically generated), as well as the strategy adopted to reduce their number (i.e. threshold on cumulative explained variance)							
	REGULATORY									
16	Legal framework	Clearly state if the software has been approved by legal authorities, e.g. Certificate of conformity (EU) or FDA approval or other, and add further details, where appropriate (e.g. risk class).	To provide information about the certification process undergone by the AI software specific version, and associated risk class for its use as declared by the manufacturer							
17	Explainability	Is the Al model explainable on the patient level or on a global or local level.	To provide a description of the methodology used to provide model explainability							
18	Ethical approval	Provide information on ethical approval of the study.	To clearly describe which entity evaluated and released the ethical approval for the study							
19	Fairness	Describe inclusion of relevant groups in the dataset	To describe the efforts made to ensure fairness in the study, including for example age, ethnicity and gender							
	OPEN SCIENCE									
20	Data availability/code sharing	Is the data available on a public website? Is the code available?	To provide details on how to access the anonymized data used for training/validating the model, as well as code sharing							
21	Trial registration	In case of a trial, clearly state if and where the trial is registered.	Provide the number and the reference for the trial registration.							
	RESULTS									
22	Participants	Baseline demographics (internal and external validation data).	To clearly describe the participant demographics in the study/trial/inclusion to perform internal validation of the Al model, as well as the dataset used for external validation."							
23	Training performance	Provide results from the training data set	To provide results using proper metrics describing the model performance when applied to the training set, in order to provide a reference for the expected model performance and allow overfitting assessment in non-externally validated studies							
24	Internal validation	The results from the testing data set	To provide results using proper metrics describing the model performance when applied to the validation set, as obtained from the same population/hospital/study/equipment							
25	External validation	The results from the external validation data set	To provide results using proper metrics describing the model performance when applied to a validation set obtained from a different population/ hospital/study/equipment							

Tab	10 7	Continued	

Item #	Category/section	Explanation	Rationale	Page no.
26	Model performance Internal and external validation	Choose appropriate metric selection for reporting	'To provide appropriate metrics (threshold dependent or independent), for example: AUC/ Sensitivity/Specificity/NPV/PPV/F1/Uncertainty Failing cases'	
27	Performance errors	Analysis of performance errors and how they were identified	To provide description about how errors in the model were detected, possible explanations, and potential corrections taken	
28	Performance compared with classic statistical methods	What did the model add?	To provide a comparison with a regular statistical model if applicable, potentially using net reclassification indices (i.e. what would have been the results of a regression model compared with the Al-algorithm)'	
29	Generalizability	Discuss the level of generalizability of the results obtained.	To discuss how and within which limits the obtained results could be generalized to a more general population, with regards to internal and external validation data sets	
ii)	CONCLUSION Conclusion	Is the conclusion supported by the dataset?		

Checklist item	In	tro						Methods									Regu	latory		Op scie		Results								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	
Al in Afib (n = 31)	100%	100%	100%	87%	71%	90%	35%	100%	84%	100%	100%	87%	42%	65%	97%	45%	87%	87%	48%	35%	6%	45%	77%	100%	58%	100%	55%	97%	87%	
Al in SCD (n = 18)	44%	67%	94%	94%	100%	100%	78%	72%	78%	89%	100%	78%	56%	50%	56%	22%	61%	78%	94%	17%	28%	83%	39%	78%	28%	67%	50%	67%	94%	
Al in the EP lab (n = 6)	100%	100%	100%	100%	67%	100%	67%	83%	100%	100%	100%	33%	17%	17%	83%	50%	67%	100%	100%	67%	33%	100%	83%	67%	17%	67%	50%	33%	100%	

**Figure 2** Overview of the application of the EHRA AI checklist in three different areas of electrophysiology. Each of the three areas are depicted in rows, and a summary of all the checklist items is provided in the columns. In each area a literature review was performed, and the summary index of the reporting of each checklist item is provided. Items reported in >85% of the reviewed papers were considered as very well reported on; items reported in <20% of the reviewed papers were considered less robust, and items between 20% and 85% were considered as intermediately well reported on. EHRA, European Heart Rhythm Association; AI, artificial intelligence.

After finalization of the EHRA AI checklist, the checklist was validated retrospectively on papers on AI in EP having been published recently. Three representative topics from the field in EP were chosen to perform a structured review of articles connected to AI for (i) AF management, (ii) SCD, and (iii) EP lab management.

For each section, studies of the respective topic were retrieved from PubMed by members of the author group. Only studies published between May 2021 and May 2024 were included to keep a contemporary focus, without intending to be exhaustive. For each study, the EHRA AI checklist was applied, and results were recorded for each item of the checklist. A summary of the results is presented in *Figure 2*. A practical example of the extraction is provided in the Supplementary material online, *Table S3*.

Detailed results of the checklist application are presented in *Table 3*.

## Al in AF management

#### Checklist application for AI studies on AF management

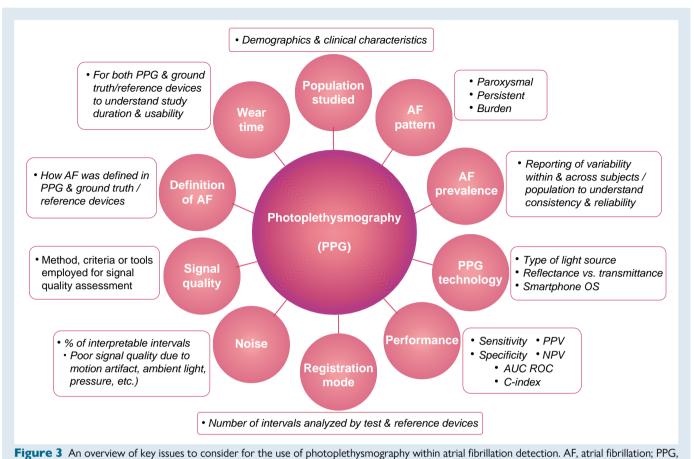
In total, 31 papers on AF management were identified (*Table 3*). Most focused on the use of AI for AF detection. The application of the EHRA AI checklist to all identified papers showed that 16 of 29 items (55%) were reported at a very good level (i.e. reported by  $\geq$ 85% of papers). The most robust reporting was for checklist items under 'methods' section with  $\geq$ 85% papers reporting 8 of 13 items (61.5%). Reporting was least robust for checklist items under 'open science'; notably, only 2 of 31 papers (6%) addressed trial registration (checklist item 21).

While reporting was generally good across methodological items, areas like open science, specifically trial registration, were poorly addressed. The lack of transparency regarding trial registration may limit

Table 3 Overview of checklist items for each extracted paper

Author	Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
AF			_			<u> </u>	<u> </u>	•																						
management																														
Baek, Y S <sup>119</sup>	2021																													
Jo, Y Y <sup>120</sup>	2021																													
Michel, P <sup>121</sup>	2021																													
Rabinstein, A <sup>55</sup>	2021																													
Bahrami Rad, A 122	2021																													
Raghunath, S 123	2021																													
Schwab, K <sup>124</sup>	2021																													
Sekelj, S <sup>125</sup>	2021																													
Taniguchi, H <sup>126</sup>	2021																													
Chen, B 127	2022																													
Kaminski, A <sup>128</sup>	2022																													
Mannhart D 129	2022																													
Noseworthy. P <sup>130</sup>	2022																				_									
Pujadas, E R <sup>131</sup>	2022																													
Schnabel, R B <sup>132</sup>	2022																													
Asadi, M <sup>133</sup>	2023																													
Gadaleta, M <sup>134</sup>	2023																													
Kim, J Y <sup>135</sup>	2023																													
Kim, Y <sup>136</sup>	2023																													
Laghari, A <sup>137</sup>	2023																													
Sarkar, S <sup>138</sup>	2023																													
Weidlich, S <sup>139</sup>	2023																													
Choi, J <sup>140</sup>	2024																													
Kim, J <sup>141</sup>	2024																													
Mandala, S 142	2024																													
Wan, X <sup>143</sup>	2024																													
Christopoulos, G 144																														
Duan, J <sup>145</sup>	2022	-																												
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Wang, Q <sup>148</sup>	2021																													
Lee, Y J <sup>84</sup>	2021																													
Smole, T <sup>149</sup>	2021																													
Krebs <sup>88</sup>	2021																													
Popescu <sup>87</sup>	2022																													
Sammani, A 77	2022																													
Balaban, G <sup>85</sup>	2022																													
O'Hara, R P <sup>92</sup>	2022																													
Ginder C <sup>83</sup>	2023																													
Lee, H <sup>150</sup>	2023																													
Shiraishi, Y 76	2023																													
Kolk, M <sup>80</sup>	2023																													
Zaidi, H A <sup>86</sup>	2023																													
Cha, Y M <sup>79</sup>	2024																													
Kolk, M <sup>78</sup>	2024																													
Barker, J <sup>75</sup>	2024																													
Holmstrom, L 67	2024																													
Coriano, M 81	2024																													
AI in EP lab																														
Liao, S <sup>100</sup>	2021																													
Baalman, S <sup>151</sup>	2021																													
Seitz, J <sup>101</sup>	2022																													
Krummen, D <sup>152</sup>	2022																													
Dokuchaev, A <sup>116</sup>	2023																													
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The extracted papers, categorized by topic area, were further divided into three distinct review areas. For each checklist item (#1–29), a colour code was assigned: green to indicate that relevant information was provided in the study, and red to indicate that relevant information was not provided.



photoplethysmography; PPV, positive predictive value; NPV, negative predictive value; AUC, area under the curve; ROC, receiver operating characteristic; OS, operating system.

the ability to track study protocols and outcomes, posing a barrier to reproducibility and potential bias in published results.

#### AF detection using photoplethysmography

The intermittent nature of AF can lead to low detection rates and inaccurate burden estimates with short-term monitoring. <sup>89,90</sup> Photoplethysmography (PPG), readily available in wearables like smartphones and smartwatches, offers semi-continuous monitoring. <sup>91,92</sup> Several consumer wrist-worn devices have been cleared by the US Food and Drug Administration (FDA) for PPG based AF detection and use Al in their algorithms. <sup>92</sup> Recent studies have evaluated the accuracy of PPG-based AI algorithms for detecting AF in ambulatory settings <sup>93–96</sup> and although PPG-based AF detection using smartphones was shown to be effective in different settings detecting or monitoring AF, <sup>5,97–100</sup> a meta-analysis of data suggested that publication bias remained. <sup>101</sup> In international guidelines for the management of AF, an ECG is still required for diagnosis. <sup>102,103</sup>

When evaluating studies focused on the detection of AF using PPG, several key areas need careful consideration to ensure clarity and precision, Figure 3.

#### ECG for detection and prediction of AF

Of the 31 identified papers, all covered the use of ECG for the detection of AF. Application of the EHRA AI checklist showed that 13 of the 29 items were reported by  $\geq$ 85% of these papers.

ECG is a common source of data, and their increasing digitization is making computerized interpretation commonplace. <sup>104,105</sup> Irregular RR

intervals during AF serve as simple inputs that can train traditional ML models for automated AF detection. <sup>3,4</sup> The loss of coordinated atrial activity in the form of 'f' waves with small voltages and the issue of noise poses greater technical challenges for which additional signal processing steps, optimization and Al-training may need to be introduced, for accurate definition and extraction. With the progression of Al/ML algorithms, including Deep Neural Networks (particularly Convolutional Neural Networks or more recent Transformer Architectures), there has been a reduction in the need for pre-processing steps and less emphasis on predefined features, which are now achieving impressive algorithm performance results. <sup>104,106</sup>

Several independent research teams have now shown that an Al-enabled ECG using a convolutional neural network could detect signatures of AF present during sinus rhythm. <sup>107</sup> It is intriguing to conceptualize that, during sinus rhythm, factors that predispose to and eventually lead to AF could be identified using Al. These include substrate abnormalities, such as myocyte changes, fibrosis and electrical/structural remodelling, or trigger factors like atrial premature beats, autonomic signatures, or multiple simultaneous non-linear signal changes not readily apparent to human readers like those seen in signal-averaged P wave properties. <sup>108</sup> This allows point of care assessment of the risk of developing AF and is particularly important, for instance, in patients with embolic stroke of undetermined source, where a positive diagnosis from documented AF poses challenges in prolonged recording, but an early Al-enhanced strategy would allow prompt appropriate treatment with anticoagulation. <sup>38</sup>

There are technical aspects of Al algorithms that need to be understood to appraise the output and their utility and clinical application.

The confirmation of ground truth in the diagnostic labelling is a prerequisite so that data with high confidence may be used to train the Al-algorithm.

## Al in sudden cardiac death

#### Checklist application for AI studies on sudden cardiac death

In total, 18 papers were identified for the field of AI in SCD. All papers focused on the use of AI for malignant arrhythmia or cardiac arrest prediction. Application of the EHRA AI checklist to all identified papers showed that 8 of 29 items (28%) were reported by  $\geq$ 85% (very well reported). The most robust reporting was for checklist items under 'methods' section with  $\geq$ 85% papers reporting 6 of 13 items (46%). Reporting was less robust for checklist items under 'open science'; notably, only 3 of 18 papers (17%) addressed data availability/sharing (checklist item 20).

The relatively low percentage of well-reported items across all sections raises concerns about the consistency and robustness of reporting practices. Poor reporting of data sharing and external validation is particularly concerning from a clinical perspective, as models that have not been validated externally may not perform well across diverse patient populations.

Data challenges in SCD studies present significant obstacles, particularly due to the rarity of events across diverse CV conditions and the prolonged time required for sufficient event accrual. <sup>109</sup> An underutilized resource in this context are historical datasets, which often include valuable ECG recordings constrained to paper formats. Ongoing efforts are focused on developing methodologies to extract and analyse data from image-based ECGs, unlocking the potential of these archival resources for predictive modelling and research in ventricular arrhythmias (VAs) and sudden cardiac arrest. <sup>110</sup>

Current clinical criteria for implantable cardioverter-defibrillator (ICD) candidacy, left ventricular ejection fraction <30–35%, captures a mere 20% of patients at risk for SCDs. <sup>111–115</sup> New markers and methods for risk-stratification of SCD are urgently needed and there is an opportunity for Al, including machine and deep learning to move towards high yield, multiparametric scores to improve accuracy of prediction. <sup>116</sup> Al tools could enable personalized risk prediction of SCD by the customization of preventive strategies based on the unique characteristics of individual patients using subtle indicators and predictors of SCD that may be overlooked by traditional analytical methods. <sup>117</sup> Recent efforts by the international PROFID consortium, using multiparameter analysis with cardiac magnetic resonance imaging (CMR) data, failed to improve risk prediction. <sup>118</sup>

### Al models for SCD prediction

Currently, the use of AI for SCD risk prediction is a burgeoning field with fewer (but increasing) publications when compared with the use of AI for AF. As such, it may be unsurprising that there was limited checklist item reporting for these papers, when compared with papers focusing on the use of AI in AF.

Screening for SCD could be performed differently depending on the population or setting:

(1) In a low-risk population (general population), the 12-lead ECG holds significant potential as a non-invasive screening modality for evaluating arrhythmic risk, primarily due to its low cost and wide-spread availability.<sup>119</sup> An ECG-AI model developed using data from two prospective, community-based studies predicted SCD with an area under the receiver operating characteristic curve (AUROC) of 0.82 in an external validation cohort over a follow-up period of 1.6 ± 2.1 years.<sup>81</sup> When combined with clinical variables, the AUROC increased to 0.90, outperforming a conventional ECG risk score based on human-interpretable ECG parameters.<sup>107,120-126</sup> In ambulatory patients, a deep learning (DL) analysis of ambulant 24 h ECG-monitoring might capture a more comprehensive reflection of electrical instability over time, as a study showed good predictive

- score (AUROC 0.80) for SCD in a heterogeneous cardiac population.  $^{80}$
- (2) In a moderate risk population (heart failure patients without ICDs), ECG-AI models outperform current clinical criteria for primary ICD implantation and traditional ECG parameters despite only achieving moderate predictive abilities. 70,75
- For high-risk patients (i.e. ICD carriers), ECG features alone do not suffice for accurate VA/SCD prediction, possibly due to the extent of baseline abnormalities in their ECG. Dynamic ECG changes over time could reflect on the changing arrhythmic substrate, potentially providing a more powerful tool as shown in a model using a dynamic Al prediction model that updated predictions with new ECG recordings, which outperformed (AUROC 0.74) a static model that used baseline information alone (AUROC 0.64).<sup>79</sup> Moreover, a DL model using intracardiac electrograms (EGMs) from ICDs accurately predicted VA treated by the ICD 3 s before onset with an AUROC of  $0.83.^{78}$  However, this performance decreased significantly to an AUC 0.55 when attempting to predict beyond a 30-day timeframe. In addition, AI could aid improved ICD patient selection by predicting non-arrhythmic mortality combining ECG and clinical data (AUROC 0.8). Another source of data is remote monitoring device data for prediction of VA and ICD therapy.<sup>82,110</sup> A study demonstrated high accuracy in the real-time prediction of imminent VA (<30 days), using remote monitoring device data including device-derived parameters such as activity levels, thoracic impedance, atrial arrhythmia burden, and lead impedance.

In addition, for patients admitted to general wards or ICUs, baseline 12-lead ECG, continuous monitoring of the heart rate and other vital signs provide opportunities for ML models to detect VAs and cardiac arrest before its occurrence, providing critical advance notice.<sup>66,119</sup>

Apart from ECGs, other data modalities, particularly cardiac imaging can provide anatomical and functional information that reflects on arrhythmic substrates. Several studies have assessed the value of CMR on VA and SCD prediction. <sup>71,77</sup> Multimodal DL models have been developed, using late gadolinium enhancement (LGE)-CMR data combined with clinical covariates. <sup>68,69</sup>

#### Future holistic representations using AI for SCD prediction

The potential of AI may be maximized when multiple modalities are integrated to construct a comprehensive characterization of the physiological cardiac state. This encompasses anatomical image features that reflect substrate-specific details such as tissue characteristics and 3D cardiac geometry, genome-wide associations studies to assess genetic predispositions, and the electrical conduction patterns and electrical physiology. Recent studies showed that neural networks can learn holistic representations across ECG and CMR, which may be associated with genetic variants. 127 An example is a multimodal Al approach (the DEEP RISK model), which integrated DL features from both ECG and LGE-CMR in patients with non-ischemic cardiomyopathy, along with clinical patient data, to predict the 1-year risk of VA (AUROC 0.84). Personalized virtual heart models (Digital Twins) that integrate cardiac imaging and electrophysiological properties have also proven effective for assessing substrate complexity, guiding VT ablation, and predicting post-ablation arrhythmia recurrence 72,129–132 Another promising avenue to explore is capturing temporal dynamics using telemonitoring and wearable devices. The risk of SCD is dynamic and fluctuates over time due to factors such as lifestyle, hormones, medication changes, progression of underlying conditions, and acute cardiac events.  $^{116}$  In addition to the information continuously captured by cardiac implantable electronic devices remote monitoring and wearable devices can register behavioral and electrophysiological data, activity patterns, or stress levels. The high volumes of data that are collected through these digital tools can be analysed through AI algorithms and leveraged for personalized prediction. Novel tools such as smartwatch-based loss of pulse detection to transform out-of-hospital cardiac arrest care by enabling early

recognition and automated activation of emergency services through Al-driven algorithms.  $^{133}$ 

#### Al in the EP lab

#### **Checklist application**

Literature review identified a total of 6 papers on the use of Al within the EP lab. Applying the EHRA Al checklist to these papers showed that 13 of 29 items (45%) were reported by  $\geq$ 85% of papers (very well reported). The most robust reporting was for checklist items under 'regulatory', with  $\geq$ 85% papers reporting 2 of 4 items (50%), followed by checklist items under 'methods' section, with 6 of 13 items (46%) very well reported. Three items were reported poorly: balanced groups, missingness/poor data (items 13 & 14 under 'methods') and external validation (item 25 under 'results'), which were reported by one paper (17%) each respectively (*Figure 3*).

In this field, regulatory items were reported more consistently, reflecting growing awareness of regulatory considerations for AI tools used in clinical environments. However, poor reporting on missing data and balanced groups suggests a need for better guidance on handling and reporting missingness, as this can significantly impact model performance and clinical utility. Similarly, external validation remains a concern, as AI models used in procedural settings must be robust across different populations and settings to ensure safe clinical application.

Overall, the ability of ML and DL to learn and automate pattern recognition of biological signals relevant to arrhythmias such as ECGs, bipolar EGM has the potential to reduce both human feature engineering and inter-observer variability in identification of arrhythmia substrates as well as improve precision of ablation targets. <sup>134</sup> New classification features of arrhythmia substrates have emerged, complementing existing electrical and imaging parameters that previously required manual or semi-automated annotation on 3D electroanatomical mapping systems during catheter ablation. <sup>135</sup>

The concept of creating a 'digital twin' of individual patients, based on personalized computational modelling, enables simulations to be performed before and after treatment of arrhythmias and prediction of response to treatment strategies, to inform and optimize pre-procedural clinical decision-making. <sup>136</sup> This methodology offers the potential for *in silico* clinical trials comparing treatment strategies without subjecting patients to the potential risk of procedural complications of catheter ablation and potentially reducing the need for further procedures if the first ablation guided by an AI method was effective.

### Al for AF ablation

Of the 6 identified papers in the review, 5 covered the use of AI in AF ablation. Of these, none reported  $\geq$ 85% of EHRA AI checklist items (range 52–83%).

An example of one of the studies is showcased in Figure 4 and Supplementary material online, Table S1. In the study a DL-based architecture for automated assessment of triggers as targets for AF ablation.<sup>83</sup>

In contrast to other studies using ML methods using retrospectively processed data off-line, the proprietary Volta software (Volta Medical) classifies intracardiac EGMs during mapping in real time with high probability of atrial spatial-temporal dispersion (DISPERS) as drivers of AF can guide catheter ablation in addition to pulmonary vein isolation (PVI) in treatment of persistent AF. A recent study analysed the outcome and safety of catheter ablation guided by the Volta VX1 software in patients with long-standing persistent AF. Among 50 consecutive patients undergoing catheter ablation for persistent AF, recurrence of any atrial arrhythmia was documented in 26 patients (52%) after a 6-week blanking period.

Tailored-AF was a multicentre RCT, using the Al-based Volta AF-Xplorer<sup>™</sup> software, which was recently presented (ClinicalTrials. gov NCT04702451). Al-guided ablation in addition to PVI showed

higher freedom from AF at 12 months than the PVI only arm (88% vs. 70% and 66% vs. 15%).

The proof-of-concept OPTIMA (Optimal Target Identification via Modelling of Arrhythmogenesis) pilot study used digital twins from imaging data to identify and refine optimal ablation targets for AF, improving treatment precision and outcomes. <sup>136</sup> The process was repeated until the substrate was no longer inducible and the final set of targets were imported into the 3D electro anatomical navigation system to successfully guide ablation. <sup>139</sup> An RCT of PVI and non-PVI substrates guided by OPTIMA is ongoing (NCT04101539).

Machine learning methods have also been applied to imaging data to identify features that may predict AF recurrence after AF ablation, including a study using DL method based on pre-ablation pulmonary vein computed tomography image that has been shown to predict recurrence of AF from non-pulmonary vein triggers in patients who received catheter ablation for paroxysmal AF. In additional studies, ML that combine LGE-CMR, <sup>132,140</sup> CT, clinical features and the body surface ECG have been shown to predict recurrence of AF after PVI better than a variety of clinical risk scores. <sup>141,142</sup> Further prospective studies are needed to validate these findings.

#### Al for VT ablation

Of the 6 identified papers, 2 covered the use of Al in VT ablation. One paper reported 18 of 29 (62%) and the other paper reported 15 of 29 (52%) of EHRA Al checklist items, neither meeting the  $\geq$ 85% threshold of very good reporting.

Machine learning methods have been applied to predict from 12 lead ECGs the site of origin of focal VT or the site of VT exit in scar-related re-entrant VT, with the aim of enabling pre-procedural planning and improving the accuracy and efficiency of localizing VT target for ablation. 144 Patient-specific virtual heart models reconstructed from CMR data, including LGE, have shown promise in improving VA ablation outcomes. These models can localize arrhythmogenic substrates and predict ablation targets pre-procedurally by simulating VT induction, helping to reduce unnecessary ablation and associated complications. Additionally, by enabling precise target localization and effective pre-procedural planning, these models can shorten procedure durations, reduce operator fatigue, and optimize resource utilization. This integration of predictive tools into clinical workflows enhances patient outcomes and represents a significant advancement in personalized EP care. 145

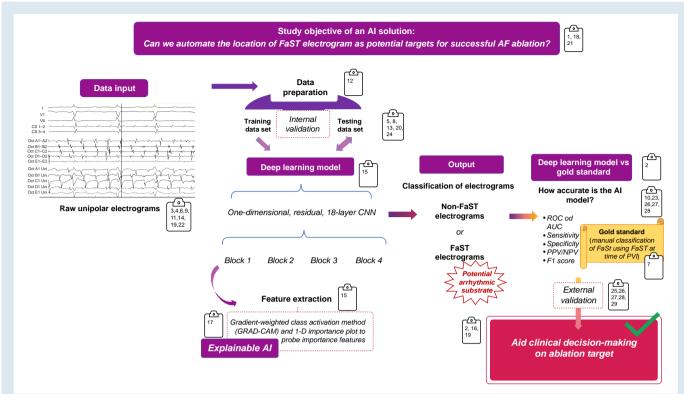
#### Al-aided 3D image integration for EP procedures

There have been significant advances in development of computing software, which can process and analyse raw image data acquired from CMR and CT scans to enable pre-procedural planning of catheter ablation. Al-guided software can quantify total scar volume, predict acute hemodynamic decompensation, <sup>146</sup> and predict post-infarct VT isthmuses <sup>147,148</sup> for successful VT ablation. Heterogeneous tissue channels can be defined and classified automatically as sub-endocardial, sub-epicardial, and transmural using Al-guided image analysis and further guide ablation. <sup>149</sup>

Recently, in a single-centre pilot study 'Ablate by LAW', it was shown that a personalized AF ablation strategy with titration of ablation index, based on left atrial wall thickness obtained from multidetector computed tomography post-processed with a software tool and integrated into a mapping system resulted in reduction in duration of procedure and fluoroscopy time, with similar rates of first pass PVI and AF recurrence to conventional catheter ablation.<sup>150</sup> There is currently an ongoing multicentre clinical trial using this approach to optimize AF ablation (NCT04218604).

## Application of AI in guiding left ventricular lead placement for cardiac resynchronization therapy

Of the 6 identified papers a single paper covered the use of AI for guidance of cardiac resynchronization therapy (CRT) lead placement. This paper reported 23 of 29 (79%) of EHRA AI checklist items.



**Figure 4** The figure illustrates the process of evaluating scientific publications on the use of AI methods in EP, based on the 29-items checklist. The numbers shown correspond with the individual checklist item numbers and where in the evaluation process they should theoretically be applied. In this example based on a study by Liao et al., <sup>83</sup> intracardiac EGMs serve as data input into a deep learning (DL) model of AI involving convolutional neural network (CNN) with the output as classification of EGMs into focal source and triggers (FaST) to identify and ablation targets. After data preparation, the data are split into a training set and a testing set for internal validation. In the training set, a DL model is developed extracting features of EGMs to differentiate FaST from non-FaST EGMs. The model then undergoes internal validation using the testing data set. The results of the internal validation are used to fine-tune the AI model to improve its accuracy. The final AI model is compared with manual classification of FaST EGMs during an AF ablation as gold standard. The accuracy of the AI model is then assessed using a standard performance matrix (AUC on ROC analysis, specificity, sensitivity, NPV, PPV, and F1 score). If the model shows good performance against a gold standard, it may provide additional clinical benefit over existing methods in automating the location of arrhythmia substrates to target AF ablation. Note that not all items on the AI checklist were reported in the study, for example, external validation, trial registration, and legal framework were not described, Supplementary material online, *Table S1*. AI, artificial intelligence; EP, electrophysiology; AF, atrial fibrillation; FaST, focal source and triggers; EGMs, intracardiac electrograms; CNN, convolutional neural network; PVI, pulmonary vein isolation; PPV, positive predictive value; NPV, negative predictive value; AUC, area under the curve; ROC, receiver operating characteristic.

Recent advancements in patient-specific cardiac modelling and ML have demonstrated significant potential to optimize left ventricular lead placement in CRT. Personalized heart models derived from MRI and CT imaging enable *in silico* simulations of electrical activation patterns under intrinsic rhythm and biventricular pacing, providing insights into optimal pacing strategies.

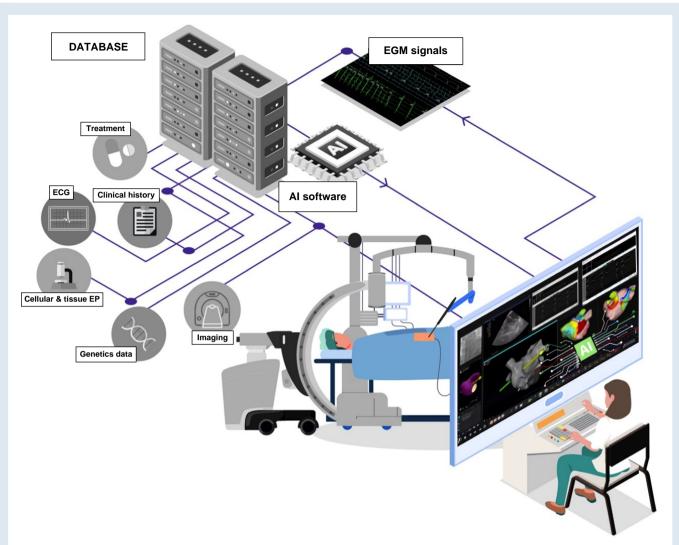
In one study, supervised ML classifiers were trained on model-derived ventricular activation characteristics combined with clinical data to predict CRT response with an accuracy of 0.77 (ROC AUC = 0.84). The ML approach identified an optimal LV pacing site that improved the predicted CRT response by 17% compared with the clinical pacing site. Additionally, 20% of non-responders were reclassified as responders when paced at the ML pacing site, demonstrating the technique's ability to refine patient stratification.

These findings underscore the utility of combining ML and personalized heart modelling to enhance CRT outcomes, improve patient selection, and refine lead placement strategies, addressing the high non-response rate in CRT.  $^{87}$ 

#### Future role of AI in EP lab

It is expected that AI will enhance several aspects of the treatment of cardiac arrhythmias in the near future. This includes refining patient selection, improving pre-procedural target identification and substrate analysis, optimizing the intraprocedural mapping process, and enabling precise assessment of ablation lesions as the chosen energy is delivered to the arrhythmia's origin (*Figure 5*). <sup>151</sup> Ideally, this approach will allow for the use of fewer catheters, enhancing patient safety and comfort while ultimately leading to better clinical outcomes. <sup>88</sup>

Looking ahead, the future role of Al in the EP lab holds significant promise. Beyond the procedural enhancements mentioned, Al has the potential to reduce procedural complexity and risk, shorten procedural durations, enhance ablative durability, and improve downstream health outcomes. Additionally, it is conceivable that data from Al-derived ECG analyses and other biological metrics could be integrated into multiparametric databases. These databases would provide a comprehensive platform for predicting arrhythmia substrates, facilitating more effective and precise catheter ablation strategies.



**Figure 5** A future vision of the use of artificial intelligence to guide robotic catheter ablation of atrial fibrillation in the EP lab using computer software that processes and analyses intracardiac electrograms in real time to indicate ablation targets. EGM, electrograms; EP, electrophysiology; ECG, electrocardiogram; AI, artificial intelligence.

To realize this vision, it is essential to adhere rigorously to standards like the EHRA checklist, which promotes reproducibility and reliability in Al-based studies. By combining visionary innovation with rigorous methodology, Al can truly transform the art and science of managing cardiac arrhythmias.

### Limitations and gaps in evidence

The current body of evidence regarding AI models in the field EP is growing but still remains limited, necessitating further research and validation. There is wide heterogeneity between studies in terms of study population, incidence of the endpoint and input data used. It is therefore critical to establish and follow standards for reporting AI studies in the field.

The application of the checklist within three key areas of EP suggests that while there is increasing awareness of methodological rigor, there are key gaps in open science and validation practices. To improve the quality of AI studies in EP, several steps could be taken:

 Journals and reviewers should emphasize the importance of trial registration, data availability, and external validation.

- Research institutions and funding bodies could incentivize these practices through funding and recognition mechanisms.
- Authors could be encouraged to adhere to reporting guidelines like the EHRA AI checklist to improve the transparency and reproducibility of their work.

The observed reporting gaps, particularly in external validation, data sharing, and missing data handling, have direct implications for clinical care. All models that are not externally validated may perform well in research settings but fail in real-world clinical practice, leading to potential risks for patients. Similarly, a lack of data availability limits the ability of other researchers to replicate findings or improve existing models, ultimately slowing the translation of Al innovations into clinical practice. Addressing these gaps through improved reporting standards would therefore contribute to safer, more effective deployment of Al tools in EP.

A further limitation of this study is the use of a threshold of >85% as a benchmark for a 'good level' of reporting, which was selected based on practical considerations but lacks a universally established justification in the context of reporting standards. While this threshold provides a useful point of comparison, further research is needed to validate its

appropriateness and to explore whether alternative thresholds might better reflect optimal reporting practices. Addressing this limitation in future efforts could help refine reporting benchmarks and provide more nuanced guidance for quality improvement in study designs.

Since the field is rapidly evolving, it could be necessary to adapt the list of items in the future. The writing group will reassess the need for adaptation at regular intervals.

Al models are not automatically the solution for all challenges in clinical EP. Al algorithms can lack transparency, making it difficult for clinicians to understand the rationale behind a model's clinical decision. Furthermore, Al models trained on specific patient populations or device types may not generalize well across diverse patient groups, EP labs, or specific catheters or devices. For example, the outcome SCD is heterogenous and includes proxies for SCD such as sustained VA, ICD therapy (shock or anti-tachycardia pacing), out-of-hospital cardiac arrest, in-hospital cardiac arrest, or any unexpected death. An Al framework trained on an imperfect ground truth, such as poorly defined or unadjudicated outcomes, inevitably compromises the reliability of the model. Many of the studies reviewed lacked proper external validation, potentially resulting in overfitting and optimistically biased model performance.

To be accurate, Al models require large, high-quality datasets for training and external validation. Effective deployment of Al in cardiac EP must therefore include rigorous validation, a collaborative approach between research groups and careful consideration of ethical and privacy concerns.

## **Conclusions**

This scientific statement on the state of art of Al in clinical EP underscores the importance of a structured and standardized approach to reporting Al-related studies. The introduction of the EHRA Al checklist for EP will improve the quality, transparency, reproducibility, and understandability of research in this rapidly advancing field. By standardizing reporting elements—such as study design, participant demographics, trial registration, Al model specifics, and evaluation metrics—the checklist seeks to address current gaps in how Al studies are reported.

Applying the EHRA AI checklist across the three areas of AF management, SCD, and the EP lab revealed several key trends. First, we observed that reporting practices are generally more robust for methodological items. This suggests that researchers in the field of AI in EP are aware of the importance of methodological rigor. However, the notably weaker reporting in areas such as 'open science' (e.g. trial registration and data availability) highlights critical gaps that need attention to improve transparency and reproducibility in AI studies. These gaps may hinder broader validation and implementation of AI tools in clinical practice, as key information about data sharing, reproducibility, and trial registration is essential to build trust and foster collaboration across institutions.

This scientific statement emphasizes that adopting this checklist widely can support the critical evaluation and validation of Al tools in clinical EP. The authors advise using this EHRA Al checklist for Al in EP studies for submission processes of manuscripts and for critical appraisal during peer review, as well as for readers of Al in EP studies for personal assessment.

Continuous validation of the checklist will ensure that it remains relevant and robust as Al applications in EP evolve. Reevaluation and refinement of the checklist may be appropriate in some years.

In conclusion, the EHRA AI checklist serves as a foundational tool for improving AI research quality in EP, fostering better collaboration, and supporting evidence-based AI implementation in clinical settings.

## Supplementary material

Supplementary material is available at Europace online.

## Acknowledgements

The authors thank the EHRA Scientific Document Committee: Prof Katja Zeppenfeld, Prof. Jens Cosedis Nielsen, Dr. Luigi di Biase, Prof. Isabel Deisenhofer, Prof. Kristina Hermann Haugaa, Dr. Daniel Keene, Prof. Christian Meyer, Prof. Petr Peichl, Prof. Silvia Priori, Dr. Alireza Sepehri Shamloo, Prof. Markus Stühlinger, Prof. Jacob Tfelt Hansen, Prof. Arthur Wilde

Conflict of interest: E.S. has received institutional lecture fees from Abbott, Astra Zeneca, Bristol-Myers Squibb, Pfizer, Johnson & Johnson. E.G.C. reports a grant in the form of a <1K€ payment to his institution from the Advisory Board on digital Health of Medtronic USA; honoraria for presentations or educational events (total <10k€) from Servier, Summeet Srl, Dynamicom Education Srl, UVET GBT Spa, Sanofi; support for attending meetings and/or travel from the European Society of Cardiology. S.E. has received honoraria (<10kEuro) from Boehringer-Ingelheim for educational events. S.E. (EHRA) is a consultant for Stereotaxis Inc, Biosense Webster and Catheter Precision and is receiving research funds from Abbott Medical. P Friedman reports research grants from Medtronic, Abbott, and has received honoraria/speaking/consulting fees from Boston Scientific, and has intellectual property rights in AliveCor, Anumana, iRhythm, Medoc, Eko, Marani, and XAI health. R.G. reports research grants from Boston Scientific, Medtronic, and Microport. H Ghanbari reports consulting engagements with Medtronic, Boston Scientific, Verily Life Sciences, Happitech, and Huxley Medical. J.K.H. (HRS), Consulting engagements with Abbot, iRhythm, Medtronic, and Vector Remote. G.H. (ESC). S.H.M. (EHRA), nil. | Millet (e-cardiology) reports grant support PID2022-142514OB-I00 from Spanish Research Agency. S.M.N. (HRS) reports grant support from the National Institutes of Health (NIH R01 HL149134, HL166260, HL83359), equity from PhysCade Inc., Lifesignals.ai, consulting from Uptodate and TDK Inc and intellectual property owned by University of California Regents and Stanford University. Professor GA Ng reports consultancy fees from AliveCor and Biosense Webster; institutional research grant support from Abbott Medical and Boston Scientific; and intellectual property owned by the University of Leicester. P Noseworthy (HRS) reports filed patents related to the application of AI to the ECG for diagnosis and risk stratification and has licensed (anlong with Mayo Clinic) several A-ECG algorithms to Anumana. P.A.N. and Mayo Clinic are involved in potential equity/ royalty relationship with AliveCor. F.V.Y.T. has received institutional lecture fees from Daiichi Sankyo, Abbott and Boston Scientific, and received unrestricted research funding from Abbott. J.R. has no conflict of interest. IP Singh is a consultant for Abbott Inc. Biotronik Inc. Boston Scientific, Carelog, Cardiologs Inc, COreDio Inc, CVRx Inc, EBR Inc, DocGo Inc, Impulse Dynamics, Implicity Inc, I-Rhythm Inc, Medtronic Inc, Medscape Inc., Microport Inc., Notal Vision, Orchestra BioMed Inc., Oura Inc, Phillips Inc, Sanofi Inc, Smart Cardia Inc and Vektor Medical Inc Research—Senti-AR, Cardiologs Inc and EBR. N.T. (HRS) is supported by NIH grants R01HL166759 and R01HL174440 and a grant from the Leducq Foundation. D.D. received modest lecture honorary, travel grants and/or a fellowship grant from Abbott, Astra Zeneca, Bayer, Biotronik, Boehringer Ingelheim, Boston Scientific, Bristol Myers Squibb, CVRx, Medtronic, Microport, Pfizer, Sanofi, and Zoll.

## Funding

E.S. is supported by the Stockholm County Council (Clinical researcher appointment), the Swedish Research Council (DNR 2022-01466), the Swedish Heart and Lung foundation, CIMED, S.E. is supported by research grants from German Center for Cardiovascular Research (DZHK), the Carl-Zeiss Foundation in the project Multi-dimension Al. | Millet (e-cardiology) reports grant support PID2022-142514OB-I00 from Spanish Research Agency. Professor GA Ng reports grant support from the British Heart Foundation [Research Excellence Award (RE/24/13003) and Healthcare Innovation Fund (HI/C2/24/360038)], the National Institute for Health and Care Research Invention for Innovation Award (NIHR204553). F.V.Y.T. is supported by personal research grants from the Dutch Research Council (NWO), Amsterdam Cardiovascular Sciences, and Health Holland. J.R. acknowledges funding from the European Union-NextGenerationEU, fellowship RYC2021-031413-I from MCIN/AEI/10.13039/501100011033, and from the European Union "NextGenerationEU/PRTR" and from grants PID2021-128972OA-I00,

CNS2023-143599 and PID2023-148975OB-I00, funded by MCIN/AEI/ 10.13039/501100011033. N.T. (HRS) is supported by NIH grants R01HL166759 and R01HL174440 and a grant from the Leducq Foundation.

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