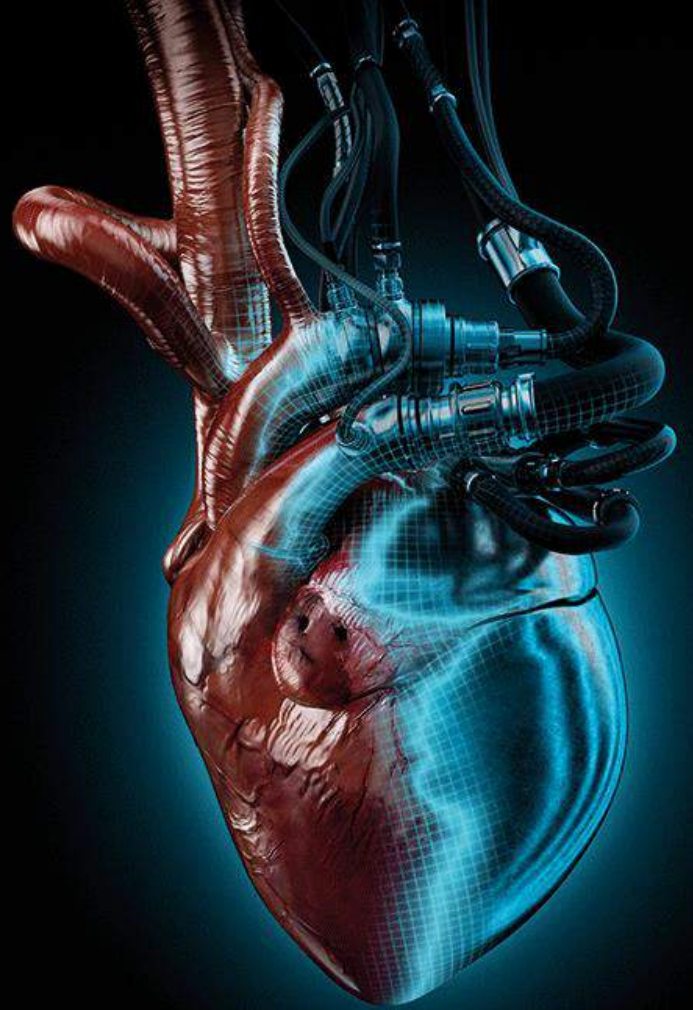
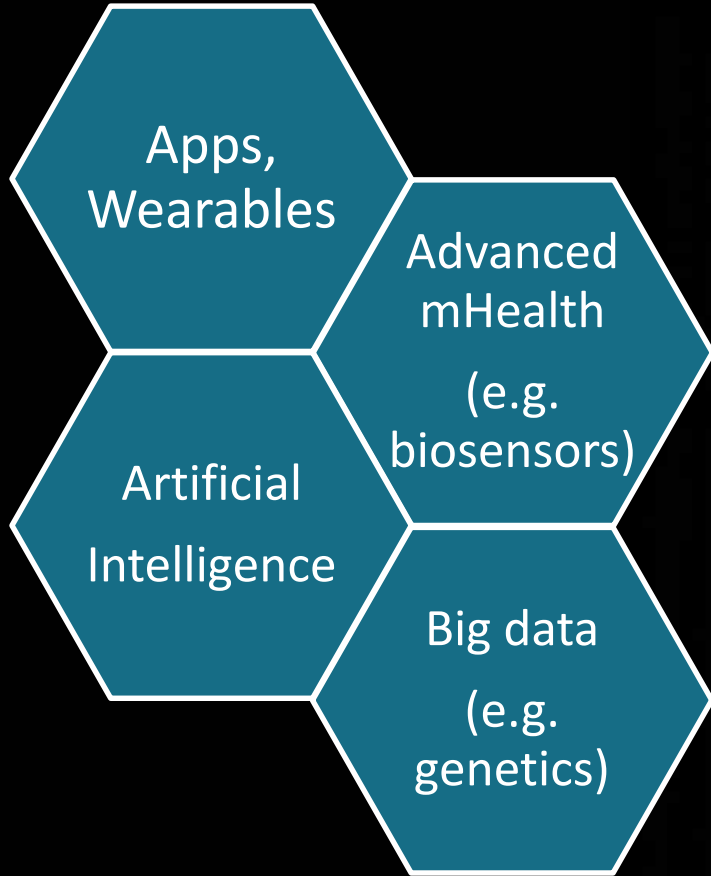


# Digital Health and Clinical Practice Guidelines

**Ulf Landmesser, MD**

ESC Clinical Practice Guidelines Committee  
Chairman, Department of Cardiology  
Charite University Medicine, Berlin, Germany





# Digital Health and Clinical Practice Guidelines

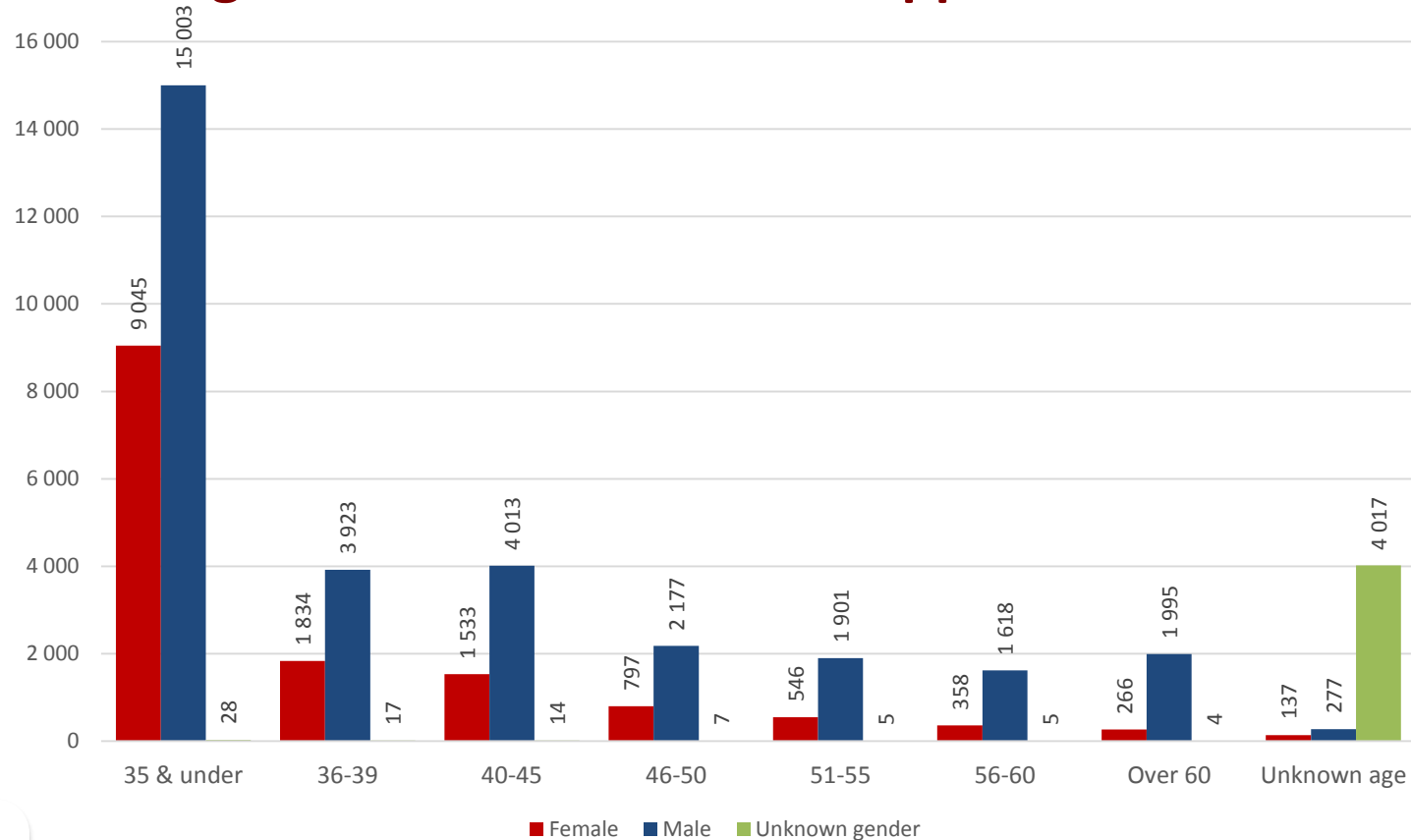
## (1) Education

- ESC Clinical Practice Guidelines Apps
- Integration of ESC Guidelines into EHR-based Decision Tools

## (2) Evaluation of Evidence for Digital Health in CVD Prevention and Management

- Mobile Health
- AI-based algorithms
- Integration of genetics

# Age and Gender of ESC GL App Users 2018



# Simplicity

- Easier and rapid access to flow-charts and tables
- Better navigation and full table view

**Dyslipidaemias**

< Total cardiovascular risk >

< Risk levels

< Risk based interven. strategies >

**Table 5 Intervention strategies as a function of total cardiovascular risk and low-density lipoproteincholesterol level**

Total CV risk (SCORE) %	
<1	No lipid intervention
Class <sup>a</sup> /Level <sup>b</sup>	I/C
≥1 to <5	No lipid intervention
Class-	

Mobile navigation bar: Home, List, Back, Forward, Search, Edit, Star, Info (16)

# **ESC Guidelines into the digital health solutions**

**ESC guidelines based decision support tools can be implemented in electronic medical reports.**

# **Digital Health – Education**

## **ESC Guidelines – Digital applications**

- **ESC guidelines Apps**
- **ESC guidelines-based decision support**

# Digital Health and Clinical Practice Guidelines

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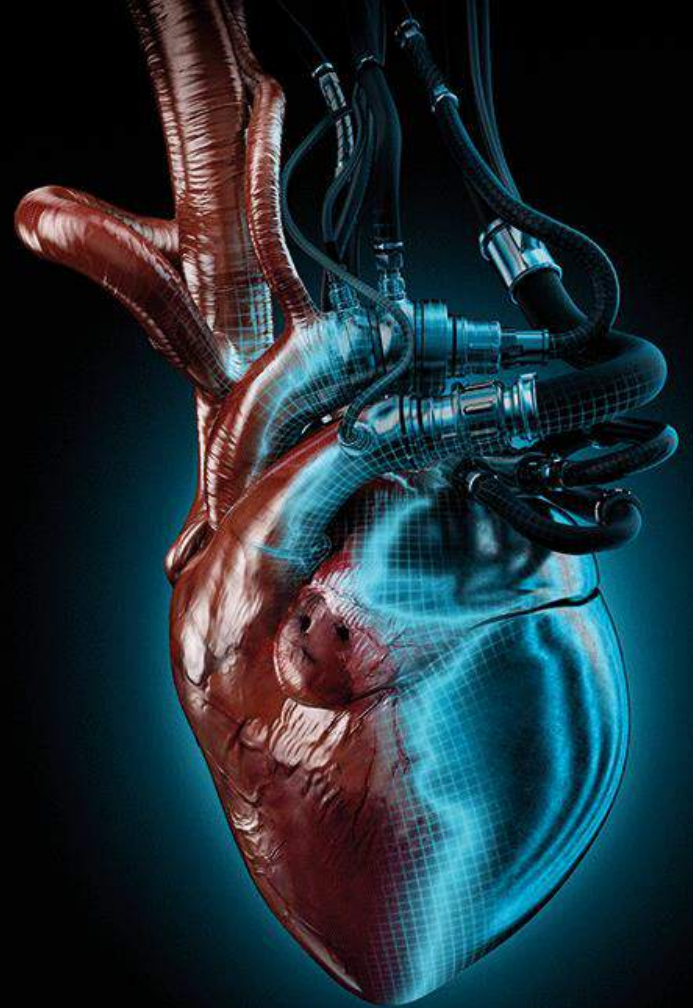
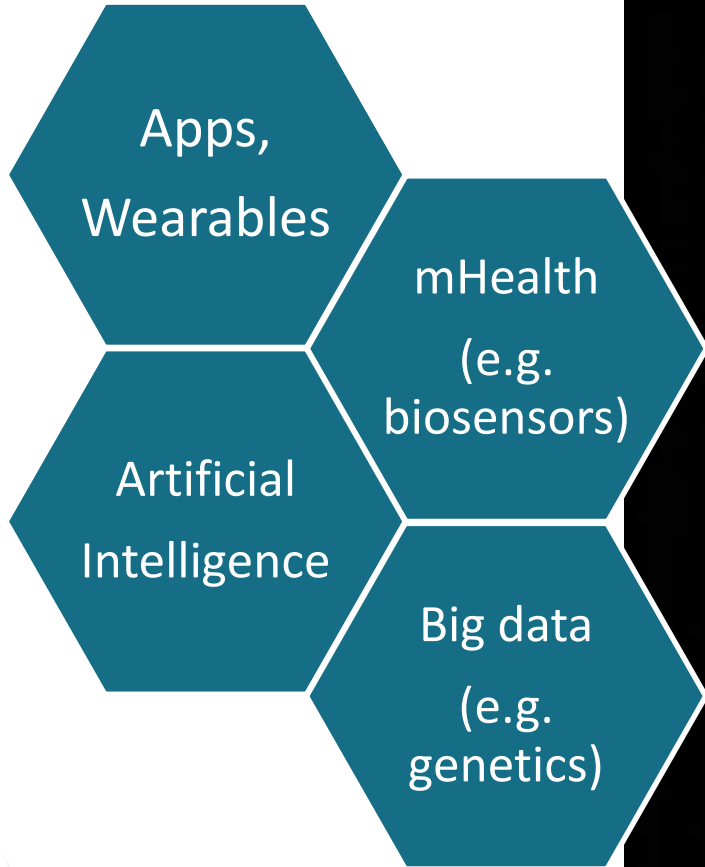
# Digital Health recommendations in Clinical Practice Guidelines

## 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

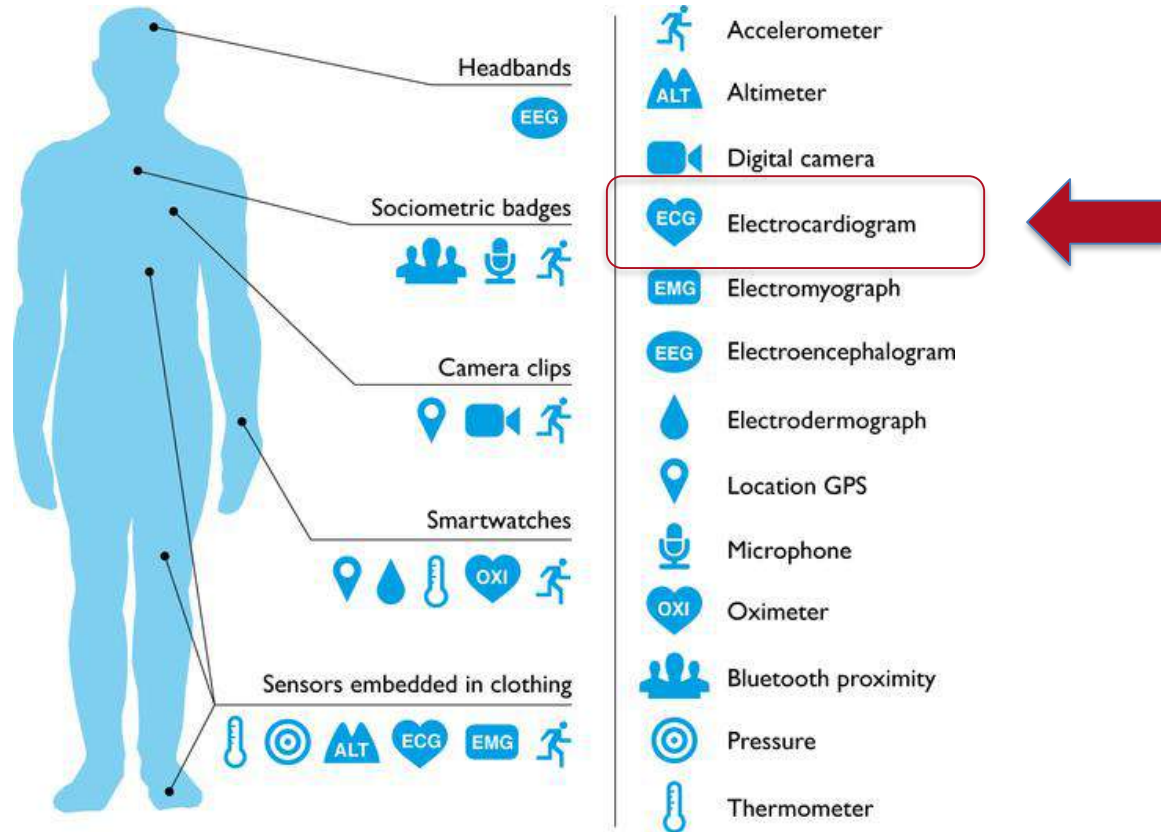
The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

Monitoring of pulmonary artery pressures using a wireless implantable haemodynamic monitoring system (CardioMems) may be considered in symptomatic patients with HF with previous HF hospitalization in order to reduce the risk of recurrent HF hospitalization.	IIb	B	628,629
Multiparameter monitoring based on ICD (IN-TIME approach) may be considered in symptomatic patients with HFrEF (LVEF $\leq 35\%$ ) in order to improve clinical outcomes.	IIb	B	630

Careful development of algorithms for remote monitoring important.



# Sensors and Biomedical Data Acquisition



# Example: Apple Watch and the Detection of Atrial Fibrillation



## HEARTLINE Study:

- Plans to enroll up to 150,000 Americans 65 and older, randomized to receive either an Apple Watch coupled with HEARTLINE app, or no watch (ECG app on the latest Series 4 Apple Watch)
- **Primary outcome:** Clinically confirmed diagnosis rate of AF ?
- **Secondary outcome:** MACE (stroke, MI, all-cause death)



# Novel approaches for detection of Atrial Fibrillation

- Dedicated ECG screening devices



- Long-term ECG monitoring



- Non-ECG technologies



# Digital technology to support self-management in patients with coronary disease



- Comments on digital health-based self-managing systems for patients with coronary disease
  - E.g. Ischemia/ACS detection
    - AngelMed (FDA approved for patients with recent ACS)
    - RELF algorithm
  - ESC guidelines recommendations ?

# ESC will take a leadership role in convergence of digital health and artificial intelligence (AI) in CVD

Comment

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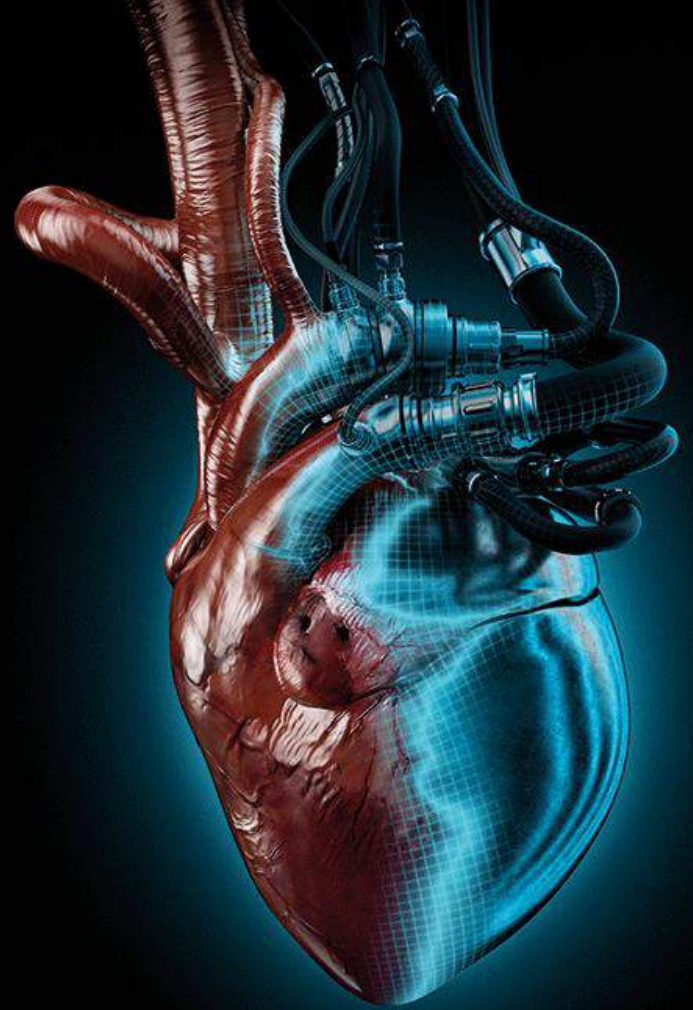
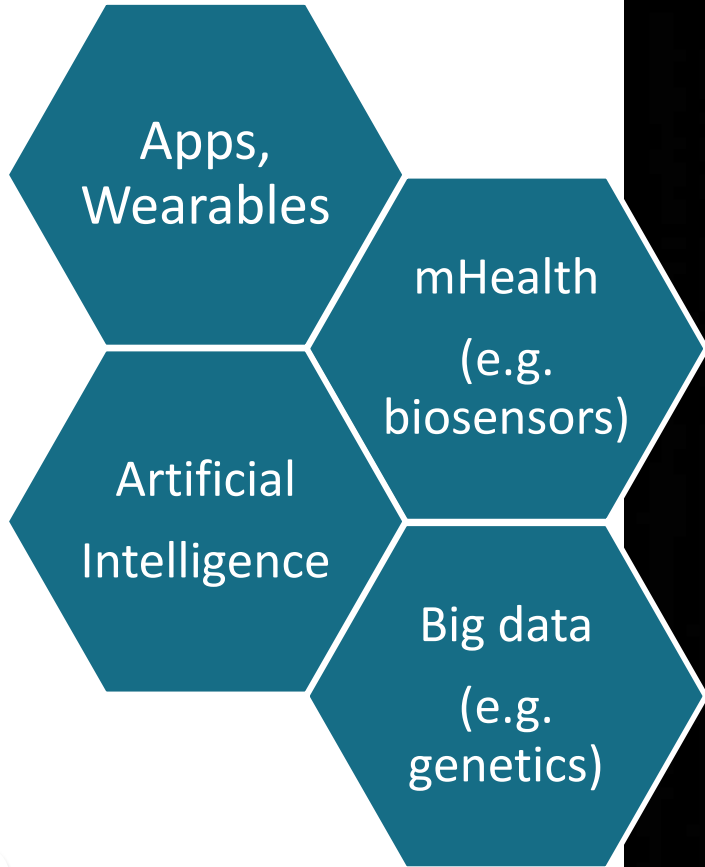
Governing health futures 2030: growing up in a digital world—a joint *The Lancet* and *Financial Times* Commission



Lancet. 2019 Sep 20 [Epub ahead of print]

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A horizontal progress bar with a red dot on the left and two grey dots on the right.





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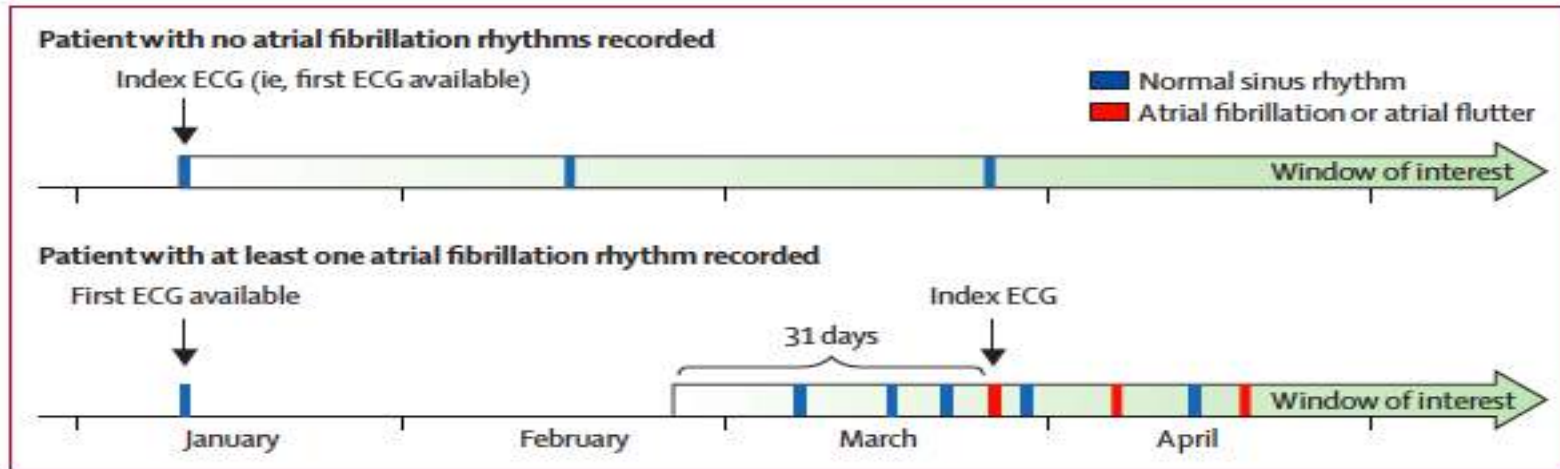
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# An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction



Zachi I Attia\*, Peter A Noseworthy\*, Francisco Lopez-Jimenez, Samuel J Asirvatham, Abhishek J Deshmukh, Bernard J Gersh, Rickey E Carter, Xiaoxi Yao, Alejandro A Rabinstein, Brad J Erickson, Suraj Kapa, Paul A Friedman



650 000 ECGs from a cohort of 180 922 patients aged >18 years

# An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction



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	AUC	Sensitivity	Specificity	F1 score	Accuracy
Main analysis	0.87 (0.86-0.88)	79.0% (77.5-80.4)	79.5% (79.0-79.9)	39.2% (38.1-40.3)	79.4% (79.0-79.9)
Secondary analysis	0.90 (0.90-0.91)	82.3% (80.9-83.6)	83.4% (83.0-83.8)	45.4% (44.2-46.5)	83.3% (83.0-83.7)

Data in parentheses are 95% CIs. In the main analysis, only the score of the first normal sinus rhythm ECG in the window of interest was used. In the secondary analysis, the highest score for all ECGs done in the first month of the window of interest was used. AUC=area under the curve. ECG=electrocardiograph.

**Table: Model performance**

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# FUTURE: Personalised Maintenance of CV Health

Genomics, Biomarkers, Advanced Phenotyping (Imaging, Digital) – Integrated by AI-based algorithms

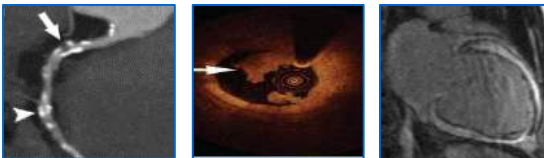


## GENOMICS



## ADVANCED DEEP PHENOTYPING

(eg Imaging of Subclinical Disease)



## CLINICAL DATA BIOMARKERS, WEARABLES



## Digital Precision Medicine:

Personalised Maintenance of CV Health/Management of CV Disease by Targeting Causal Pathophysiological Mechanisms of Disease Progression

**Novel Artificial Intelligence-Based Algorithms**

Adapted and modified from :

Leistner D, Landmesser U.  
**Eur Heart J** 2019; 40: 9-12

# ESC-CPG Methodology Task Force

Started in 2018, will provide a document for  
methodology for ESC Clinical Practice Guidelines

# Topics of Methodology Consensus Document

## Levels of Evidence/Grading

- Therapeutic decisions
  - Meta-analyses vs single RCTs
  - Role of observational studies
- Prognostic information
  - RCTs not required
- Diagnostic tools
  - When are observational studies enough?
  - When are RCTs required?



# Levels of Evidence/Grading for Therapeutic Decisions

## ➤ Meta-analyses

➤ Based on systematic review

➤ Size of 2 largest trials (patients, events)

➤ Funnel plot

➤ Heterogeneity between trials:  $I^2$ ,  $\tau^2$ ,  $\tau$

➤ Effect estimate (HR, RR etc.)

➤ 95% confidence interval or p-value as evidence against null hypothesis ( $p < 0.005$ )





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