



EUROPEAN MEDICINES AGENCY

Amsterdam, July 1st, 2026

Clinical Research – Opportunities and Challenges

Thomas F. Lüscher, MD, FRCP, FESC
ESC President

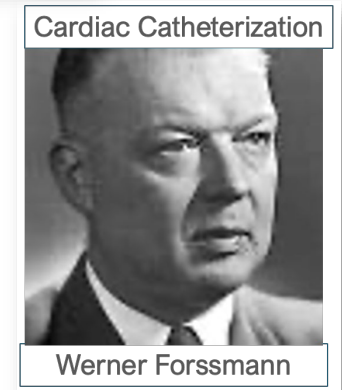
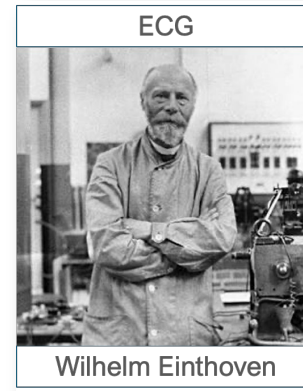
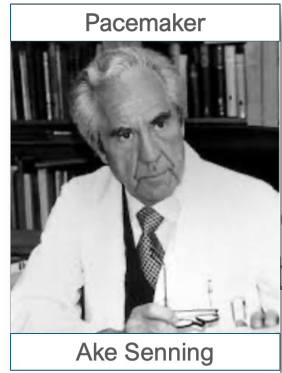


Content

- The European Legacy in CV Research and Medicine
- Cardiovascular Disease are still a Major Cause of Mortality
- The Unmet Medical Needs
- The new Challenges
- The Digital Transformation
- The European Unions Actions
- Outlook

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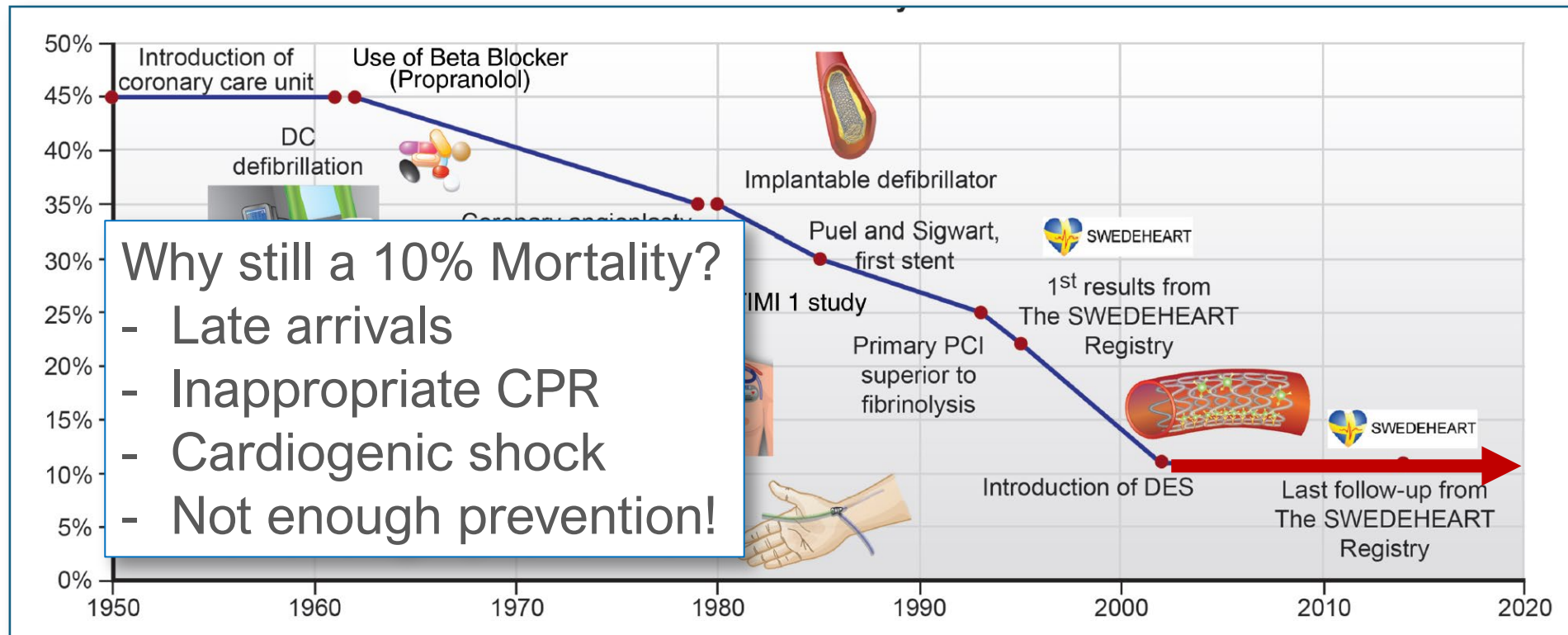
The Advent of cardiovascular medicine.....



..... in Europe!

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From the 1950ties to moden ACS Management

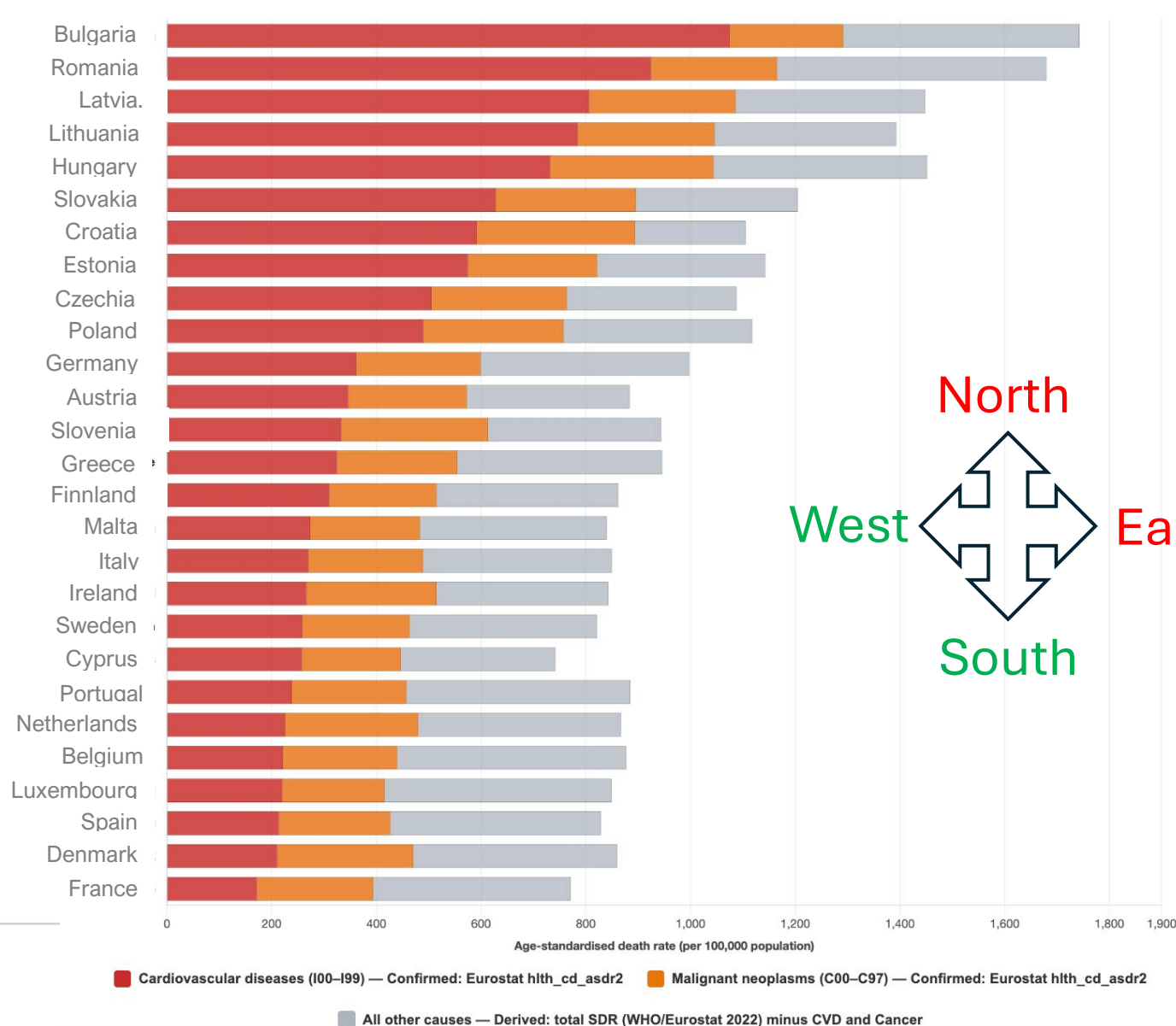


T.F. Lüscher and S. Obeid. Eur. Heart J. 2027

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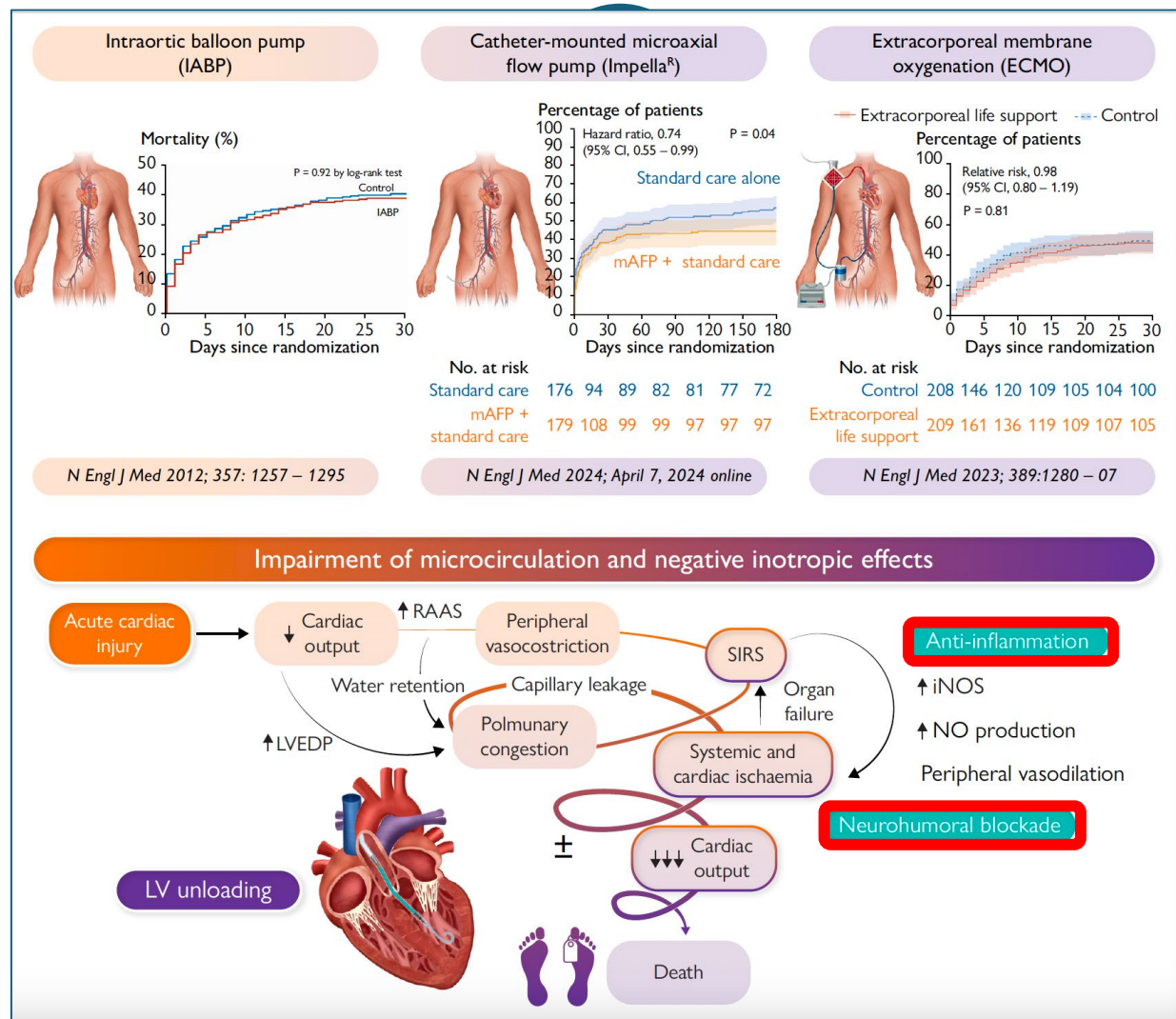


shutterstock.com - 2646019773

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Cardiogenic Shock – the biggest need!



Sudden Cardiac Death in Europe

The Epidemiological Burden

~300,000

deaths / year

EU general population

Every

2 minutes

one SCD occurs in Europe

<10%

survival rate

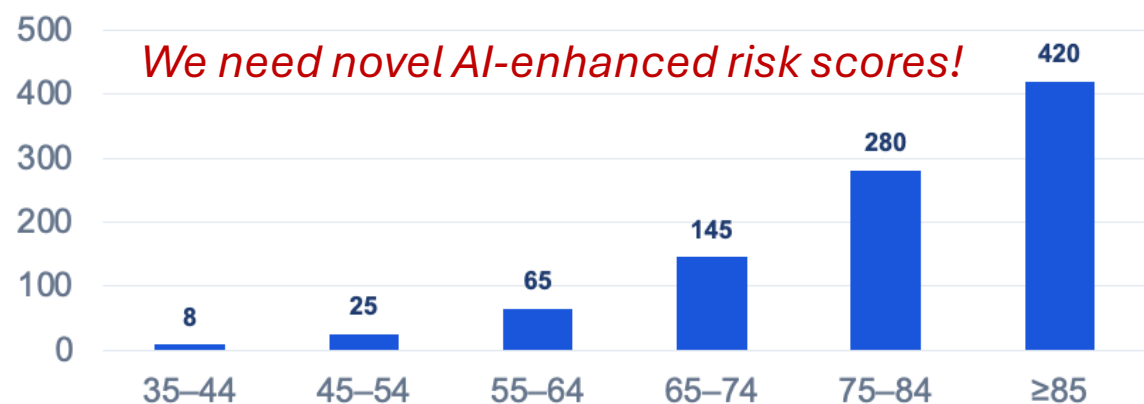
out-of-hospital cardiac arrest

2 : 1

male : female

male predominance across ages

Age-Specific SCD Incidence (per 100,000/year)



Key Facts

- ▶ 3rd leading cause of death in Europe (ERC Guidelines 2021)
- ▶ ~86 per 100,000/year for all out-of-hospital cardiac arrest (EuReCa ONE)
- ▶ Coronary artery disease: ~80% of underlying aetiology
- ▶ Biphasic trend: decline until 2013, sustained rise thereafter (Lancet Reg Health Eur 2026)
- ▶ SCD as first cardiac manifestation: up to 50% of cases
- ▶ Globally: 4-5 million SCD/year (Lancet Commission 2023)

Sources: Behr ER et al. JACC 2022;79(20):1999-2009 · EuReCa ONE Collaborators. Resuscitation 2016 · Lancet Commission on SCD, Lancet 2023;402:883-936 · Trends in sudden death-attributed mortality, Lancet Reg Health Eur 2026

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Sex and Cardiovascular (CV) Disease

Male CV Patients



Hypertension
Not applicable
Diabetes
Coronary Artery Disease
Acute Coronary Syndromes
Takotsubo Syndrome
Spontaneous Coronary
Artery Dissection
Arrhythmias
HFpEF
HFrEF
Diverse Tumours and CVD

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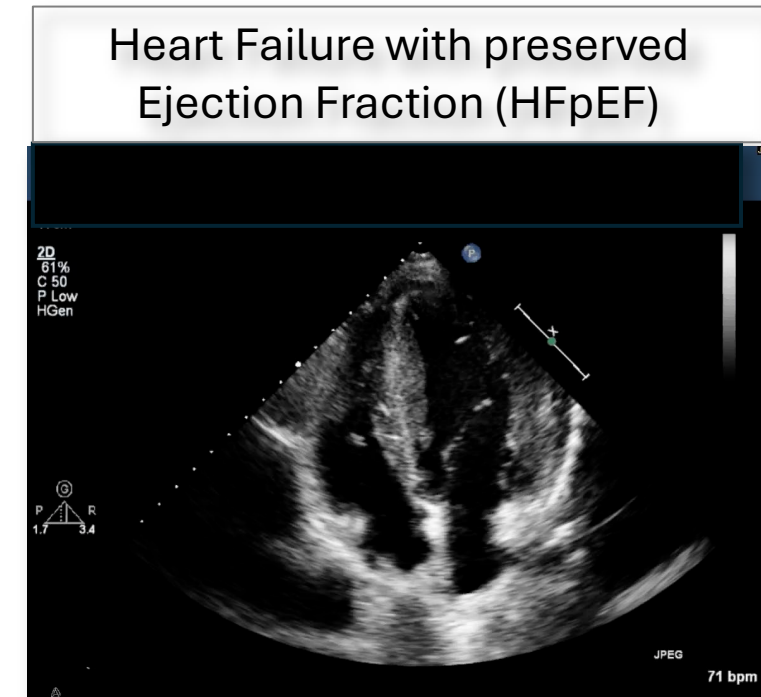
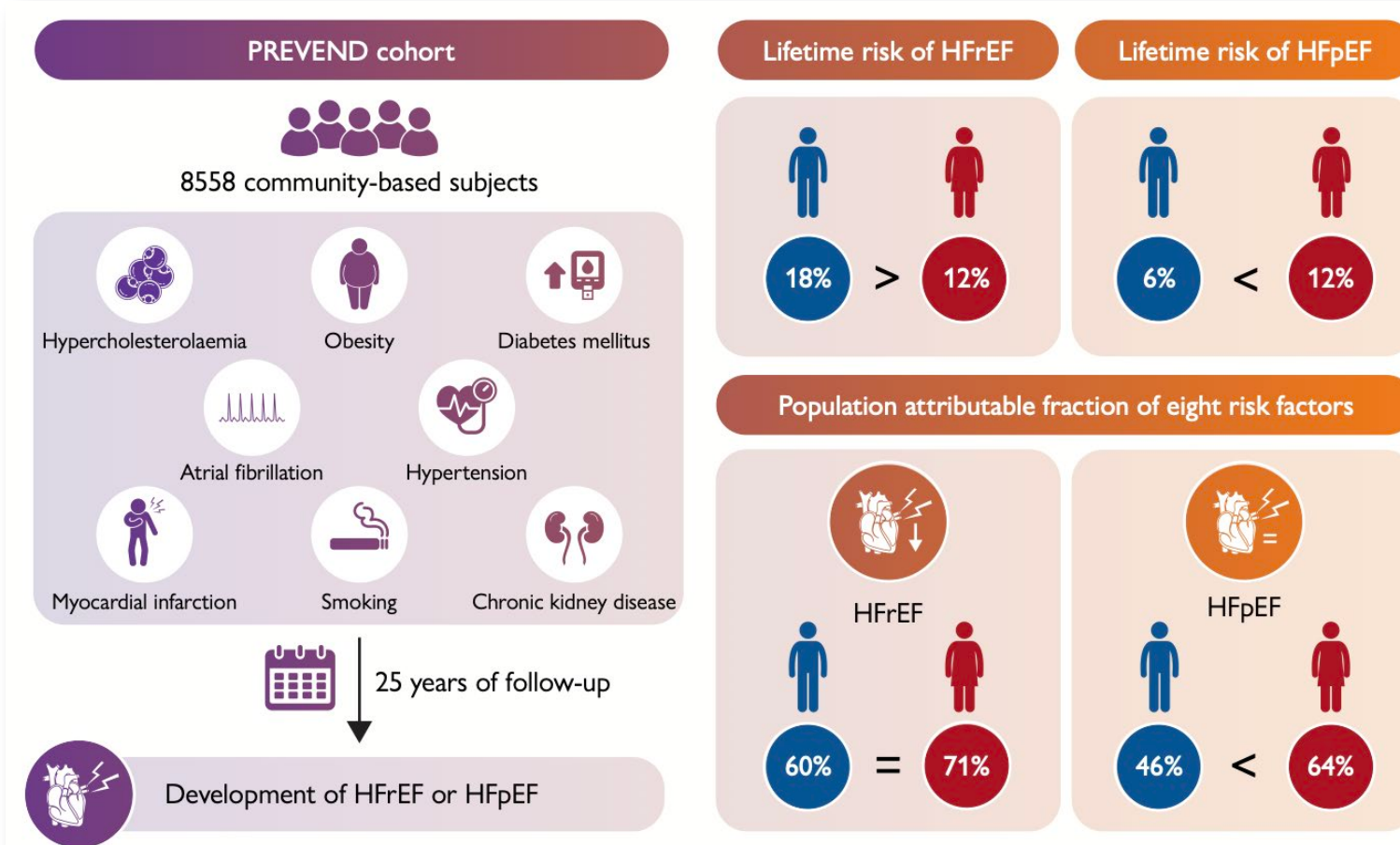
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Female CV Patients



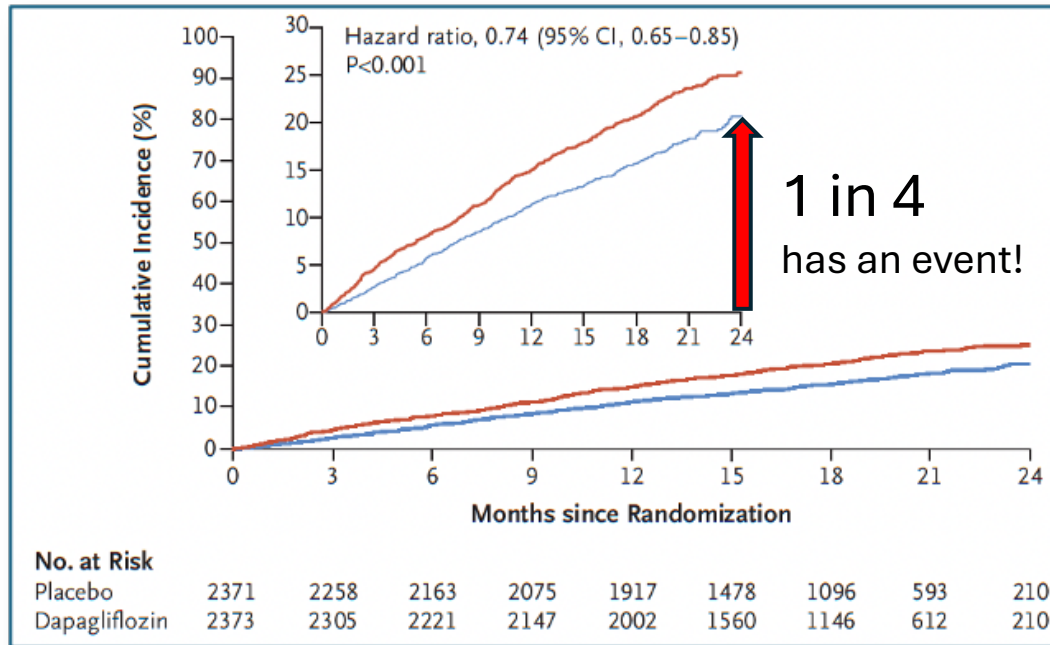
Hypertension
Pregnancy-associated HTN
Diabetes
Coronary Artery Disease
Acute Coronary Syndromes
Takotsubo Syndrome
Spontaneous Coronary
Artery Dissection
Arrhythmias
HFpEF
HFrEF
Breast Cancer and CVD

Heart Failure a Condition with a Sex Twist



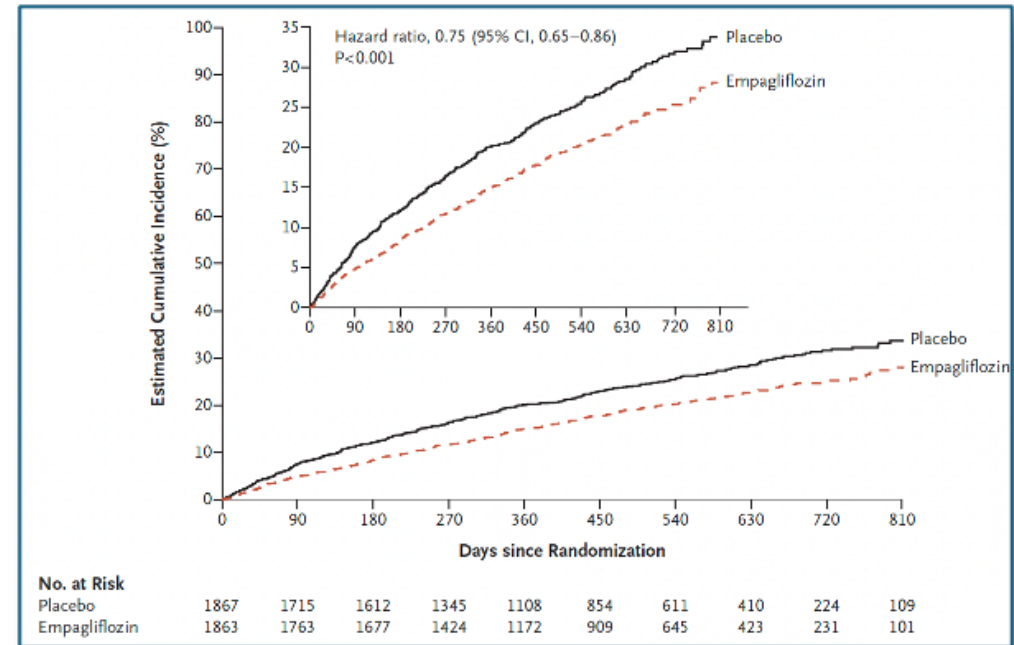
Heart Failure a big Success with Fatal Outcomes

Dapa-HF

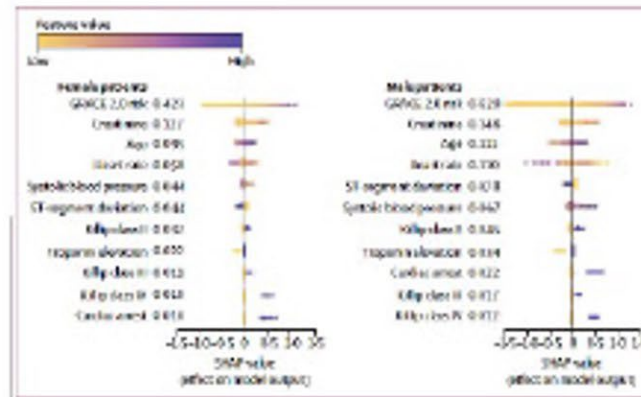


N Engl J Med 2019;381:1995-2008.

Empa-Reduced



N Engl J Med 2020;



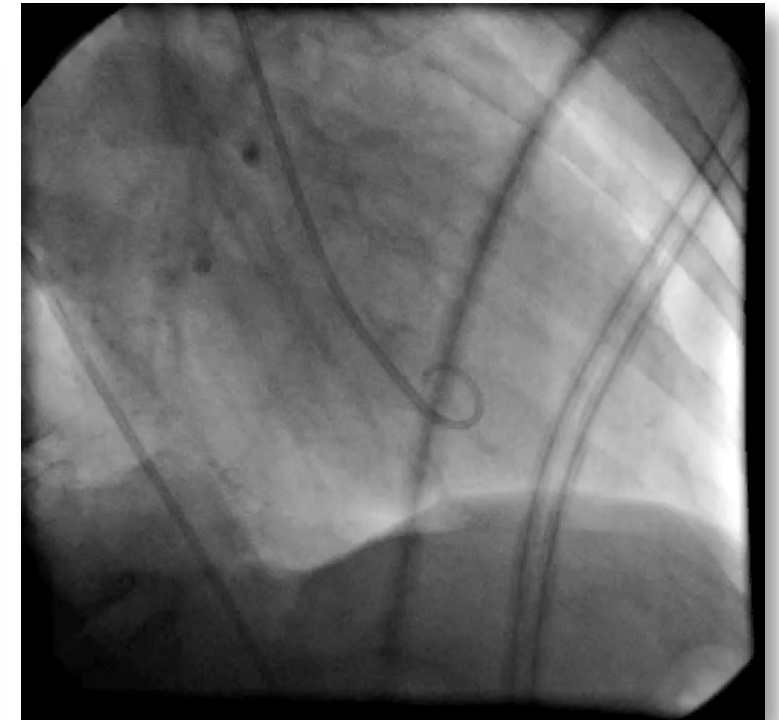
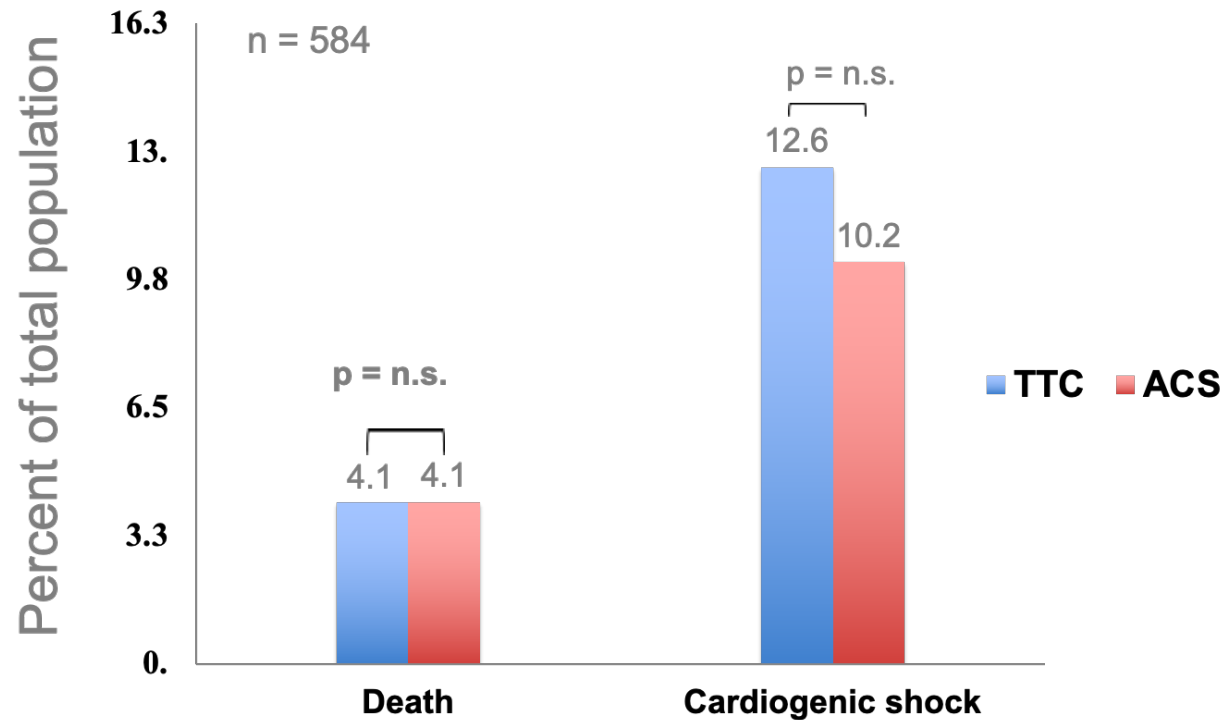
Clinical features and internally calculated GRACE 2.0 risk estimates informing supervised ML model ranked according to their contribution to the model output. Each point represents a patient. Colour indicating the feature value, e.g. effect of age on model output is positive when the patient is relatively old (purple) and negative when a patient is relatively young (yellow).

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

In-hospital Outcome compared to ACS



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Depression

Anxiety

Frustration

Depths

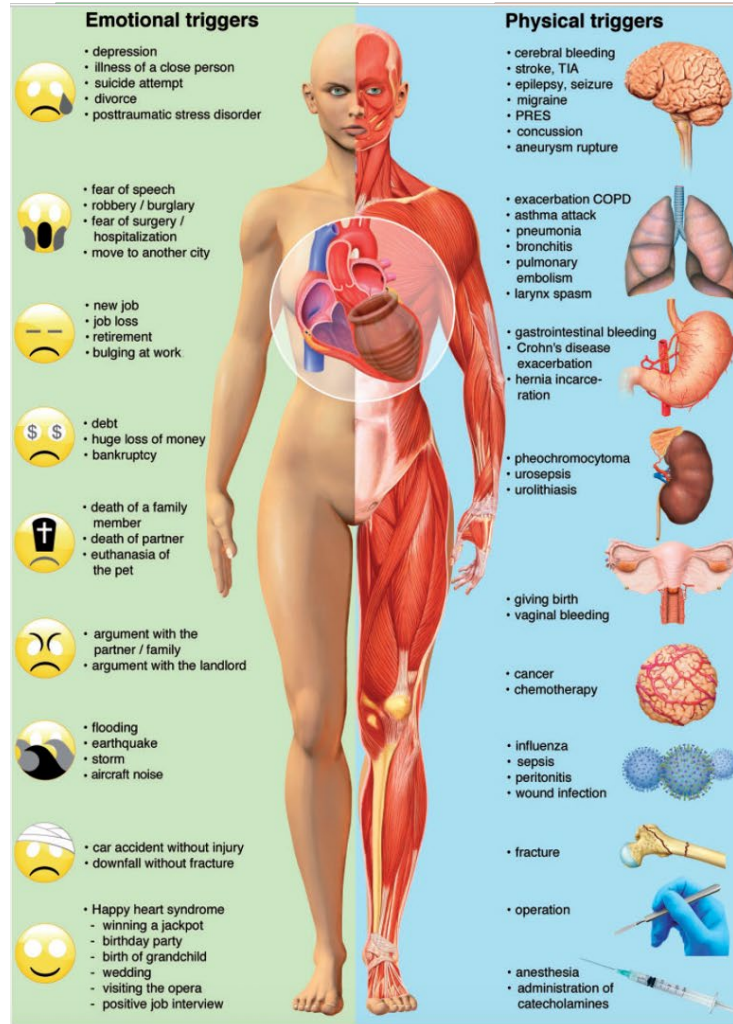
Grief

Conflicts

Natural
Disasters

Accidents

Joy, Surprise



Neurological
Illness

COPD, PE
Pneumonia

GI Bleeding
Crohn's Disease

Pheochromocytoma

Delivery

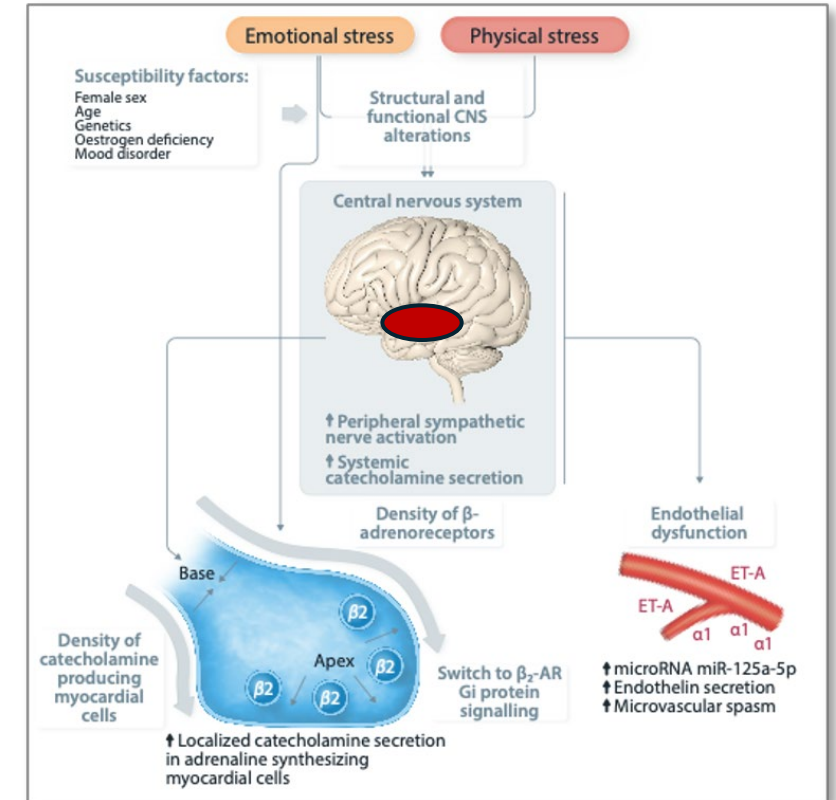
Tumours
Chemotherapy

Virus Infection

Fracture

Operation

Anesthesia

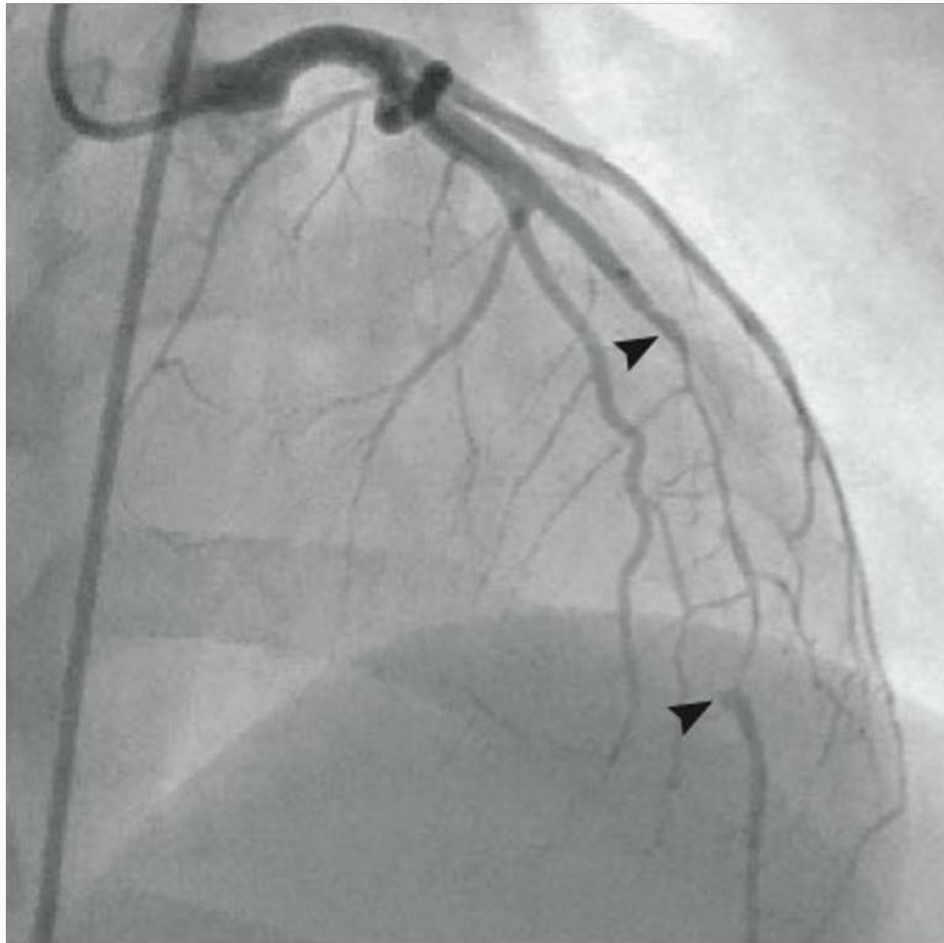


Akthar M Mand Lüscher TF:
Cardiovasc. Res. 2023

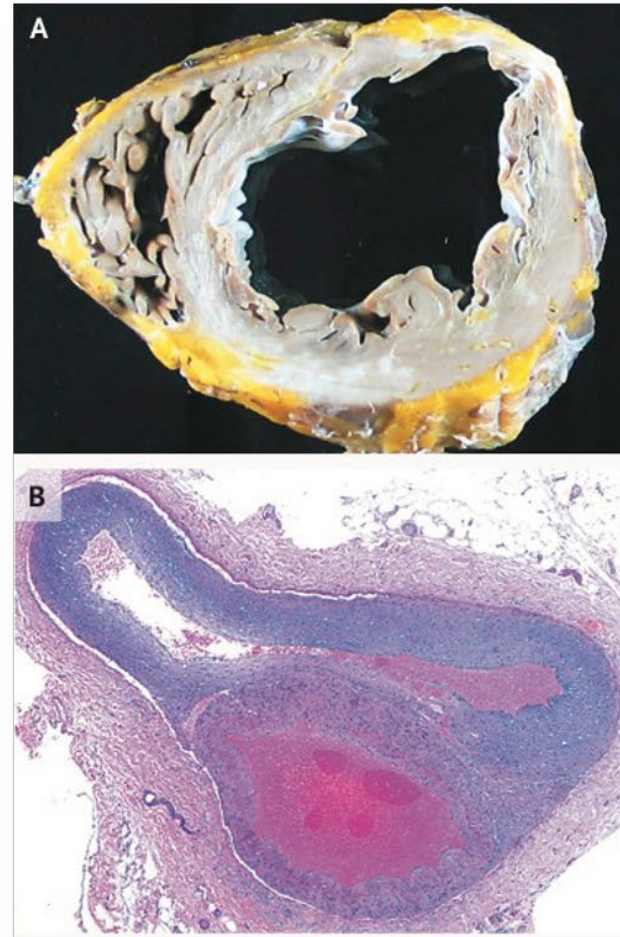
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Spontaneous Coronary Dissection (SCAD): Phenotyp and Causes

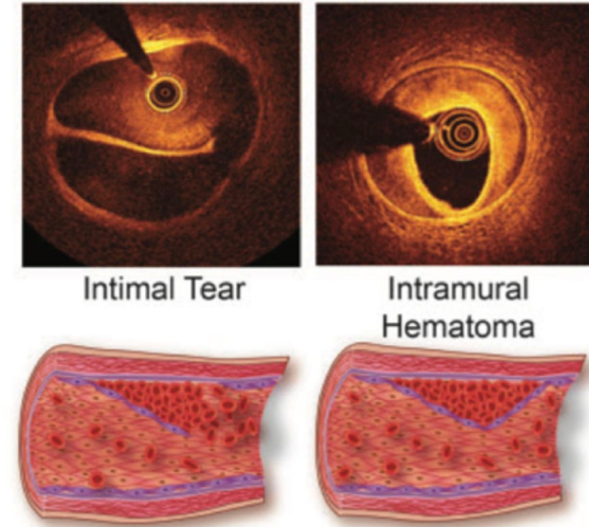
Angiographic Presentation



Pathology



?

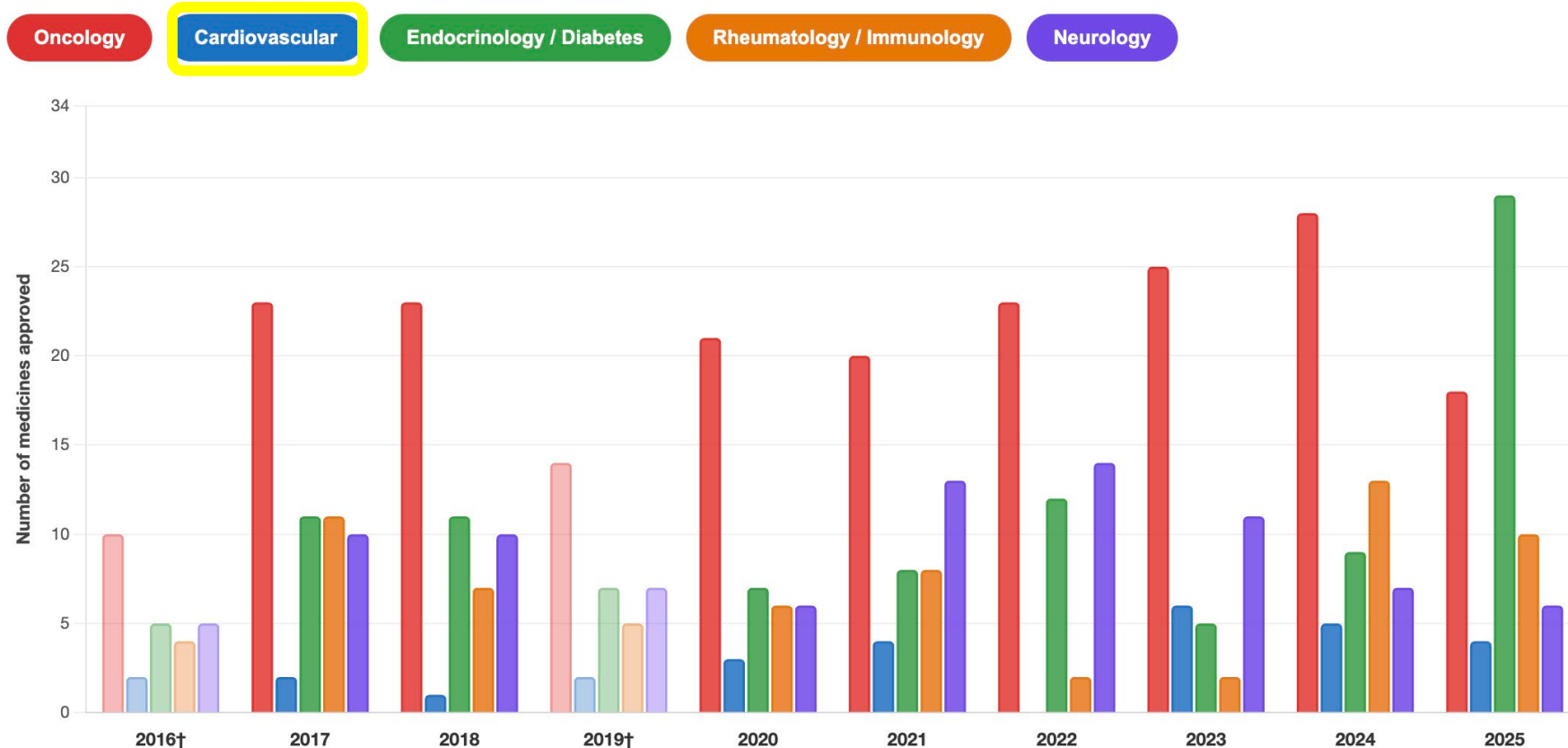


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Number of Registered Medications in different Medical Specialites

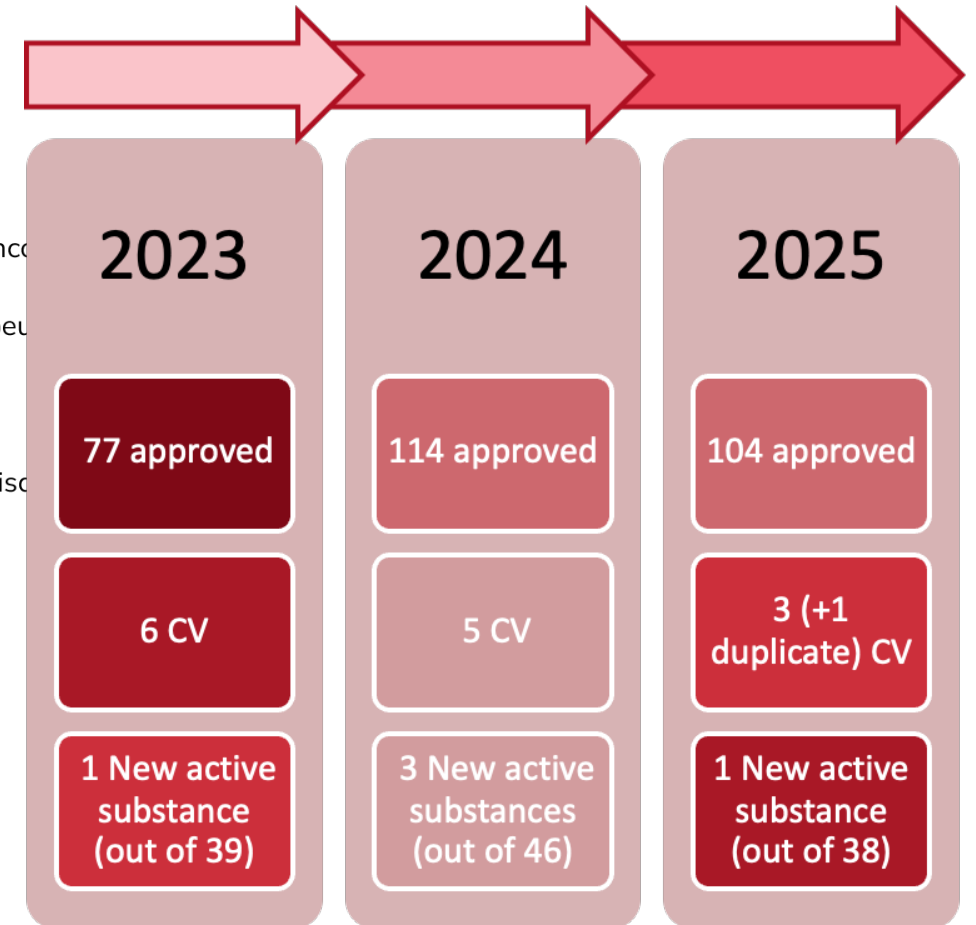
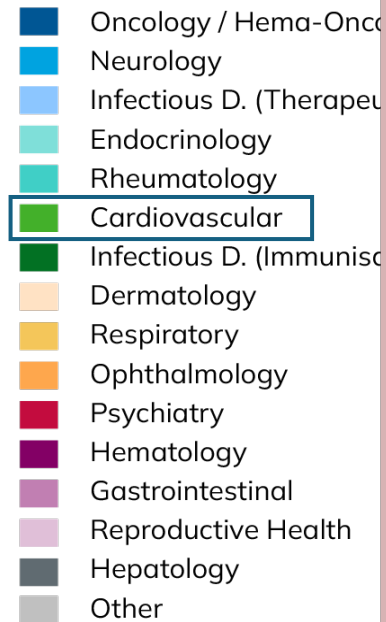
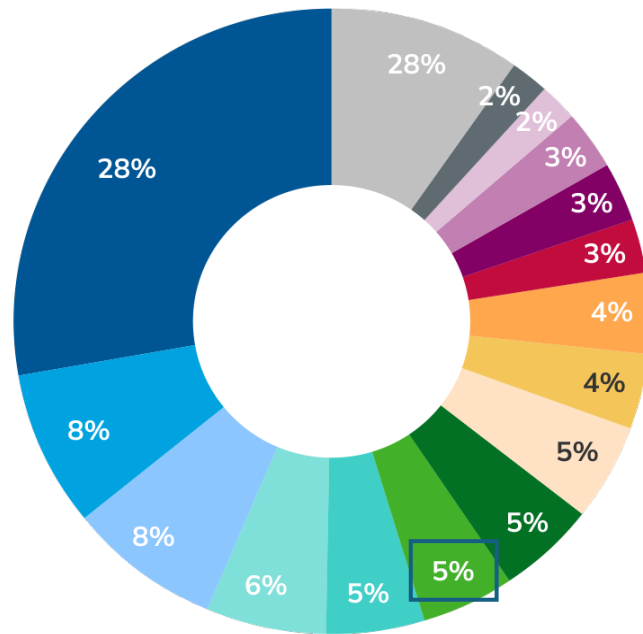


† Years 2016 and 2019 are interpolated estimates (EMA breakdowns by therapeutic area not available in published highlights). All other years are derived from primary EMA documents.

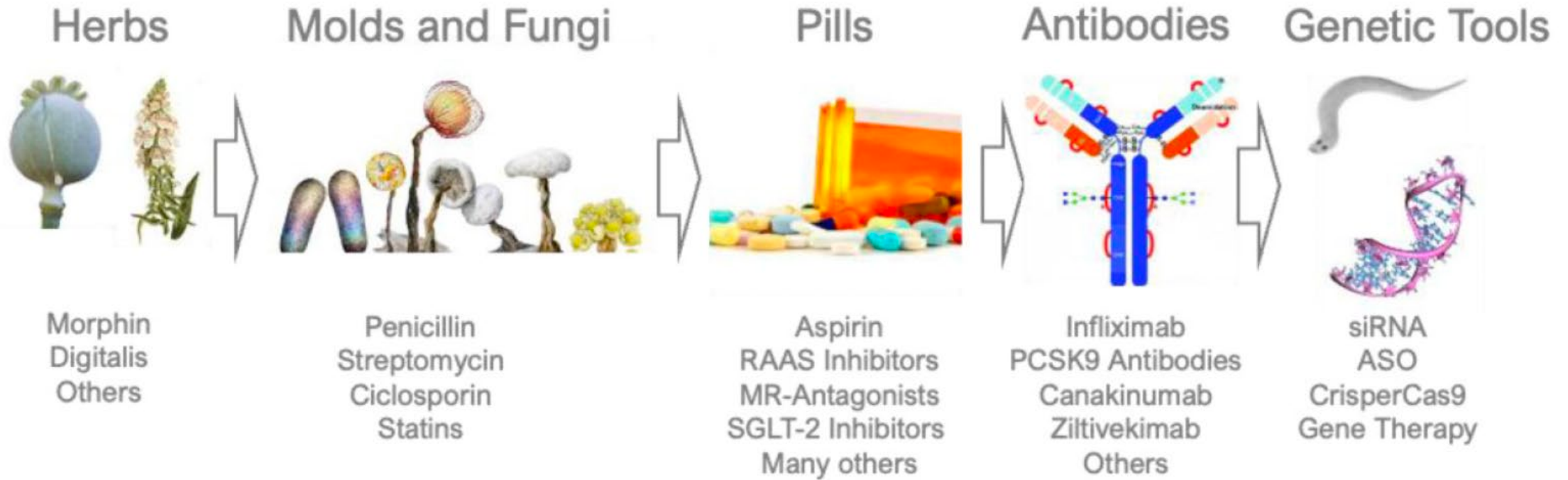
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No. Clinical Trials by Therapy Area

(Phase 1~3, Global, all trials conducted 2018~2023)*¹



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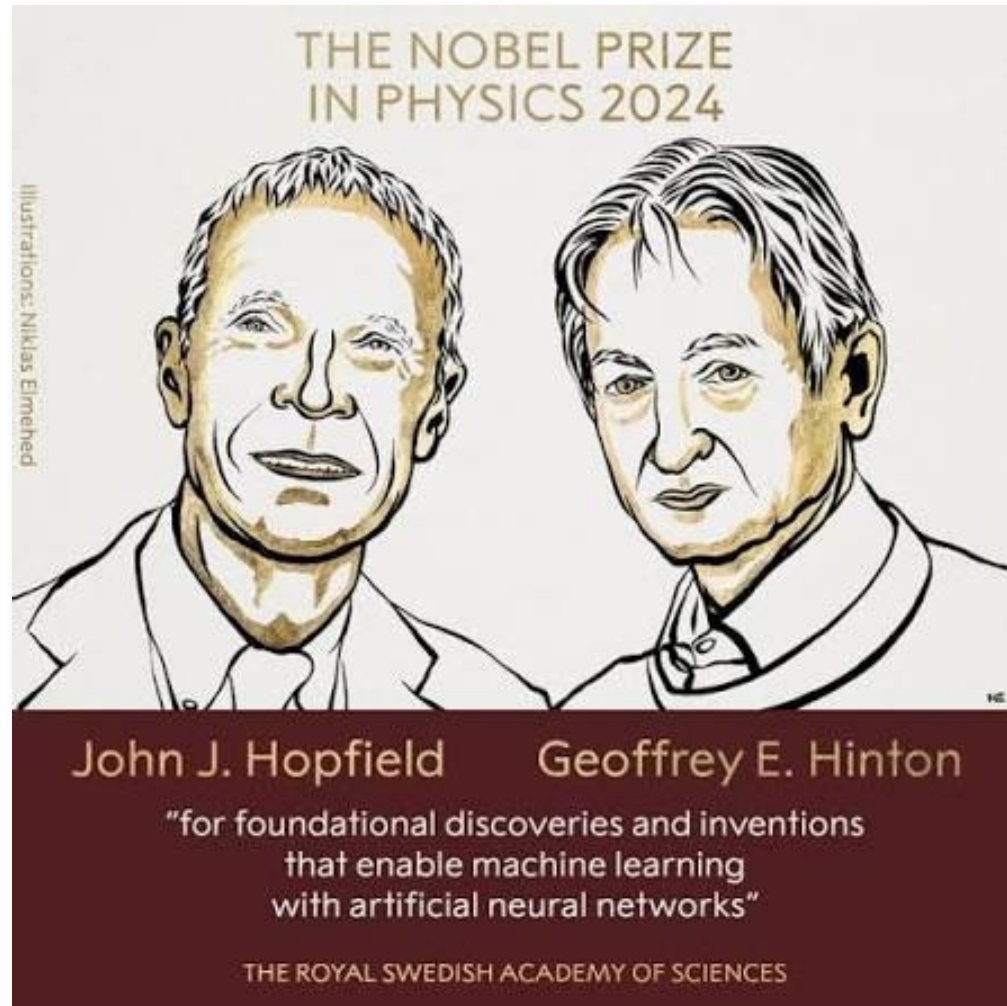


From tender loving care to treatment and cure!

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 **ESC**
European Society
of Cardiology

European Heart Journal (2025) 46, 677–679
<https://doi.org/10.1093/eurheartj/ehae748>

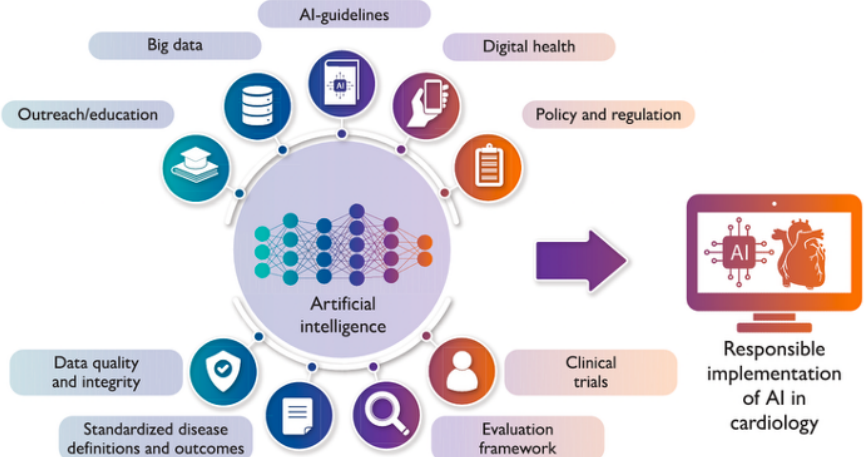


ESC News

Trustworthy implementation of artificial intelligence in cardiology: a roadmap of the European Society of Cardiology

Folkert W. Asselbergs ^{1,2,3,*} and Thomas F. Lüscher ^{4,5,6,7}

Artificial Intelligence in Cardiology: A Roadmap of ESC



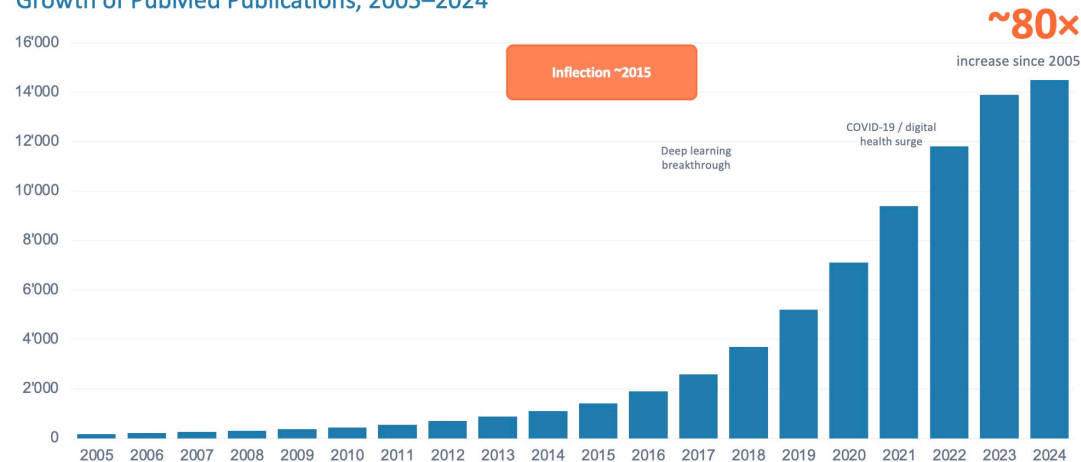
Responsible implementation of AI in cardiology

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The Digital Transformation of Cardiovascular Medicine

AI in Cardiovascular Medicine

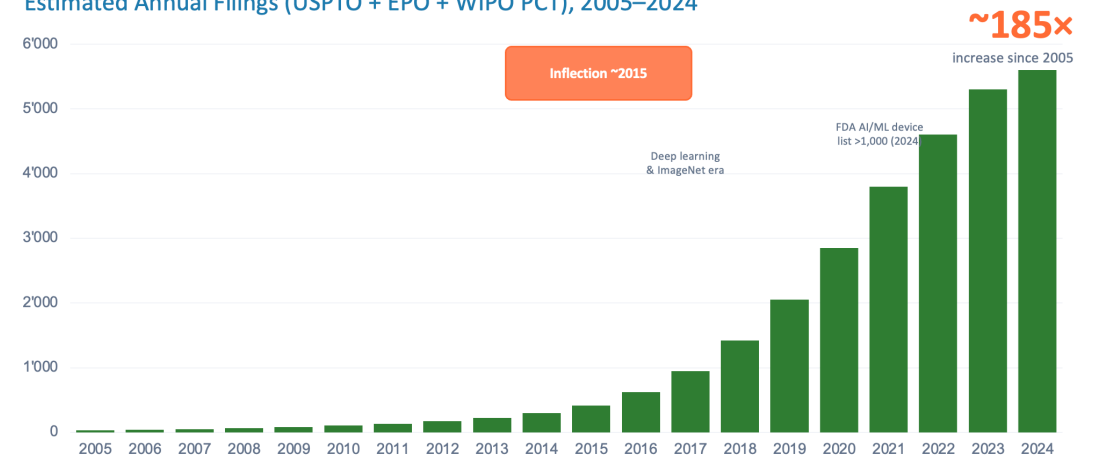
Growth of PubMed Publications, 2005–2024



Approximate annual PubMed count: AI + machine learning + deep learning × cardiovascular/cardiology (all fields). Based on: Suero-Abreu et al., Am Heart J Plus 2022; Sidik et al., Cureus 2024; Jiang et al., Front Cardiovasc Med 2025.

AI Algorithm Patents in Cardiovascular Medicine

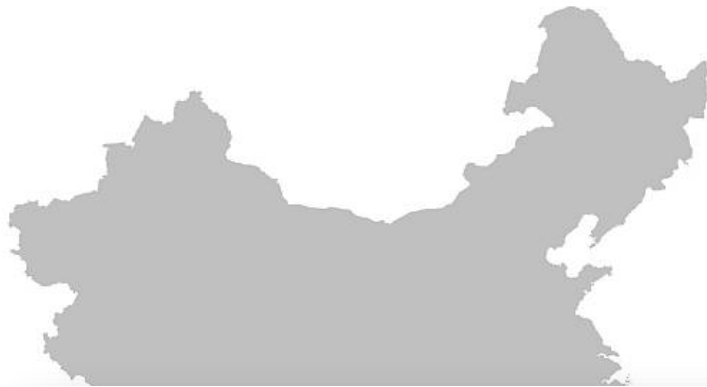
Estimated Annual Filings (USPTO + EPO + WIPO PCT), 2005–2024



Approximate combined filings (USPTO + EPO + WIPO PCT): AI/ML algorithms × cardiovascular indications. Based on: USPTO AIPO 2023; Cascini et al., J Med Internet Res 2024 (PMIC11041483); WIPO IP & Health; AIPPI AI in Healthcare 2025.

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AI/ML around the World



Chinese AI Companies

AUTONOMOUS DRIVING	SMART CITY	MEDICAL IMAGING	SMART AUDIO	SMART VISION
百度	Alibaba Group	腾讯	科大讯飞	商汤
VISION COMPUTING	SMART MARKETING	SOFTWARE/ HARDWARE	INCLUSIVE FINANCE	VIDEO PERCEPTION
依图 YITU	明略科技	HUAWEI	平安好医生	HIKVISION
SMART SUPPLY CHAIN	IMAGE PERCEPTION	CYBERSECURITY	SMART EDUCATION	SMART HOME
京东	MEGVII 旷视	360 奇酷	TAL 好未来	mi xiaomi



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ESC
European Society
of Cardiology

The ESC

Congresses & Events

Journals

Guidelines

Education

Research

ESC Digital & AI Summit 2026

12-13 November
Basel, Switzerland

#ESCAIsummit26



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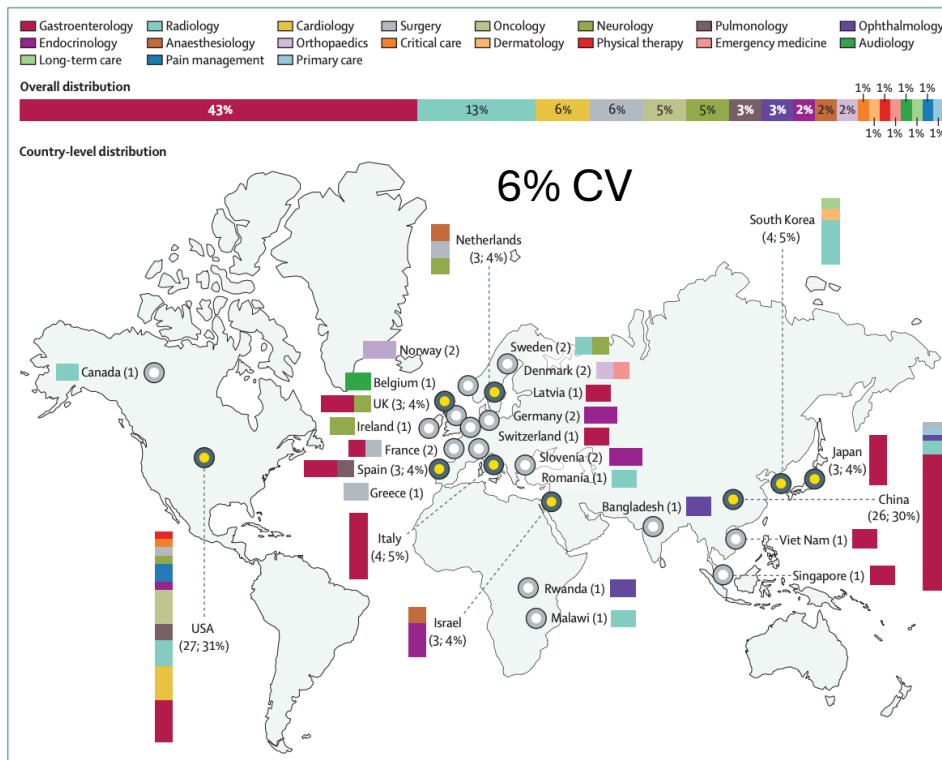


The **EU AI Act** (Regulation 2024/1689) is the world's first comprehensive legal framework regulating AI. It employs a strictly **risk-based approach**, i.e. the severity of the rules directly scales with the potential for societal harm. With **health care being high risk**. The regulation entered into force on 1.8.24, with rules phased in upto 2027.

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Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review

Ryan Han, Julián N Acosta, Zahra Shakeri, John P A Ioannidis, Eric J Topol*, Pranav Rajpurkar*



1. RCTs Using AI Algorithms in Cardiology
2. EchoNet-RCT (ESC 2022 / *Nature Medicine* 2023)
3. AI-Echo RCT (*JAHA* 2026)
4. VITAL-AF (*Heart Rhythm* 2022 / sub-analyses ongoing)
5. AI-ECG for AF & OAC Adoption (*JAHA* 2025)
6. Lancet AI-AF Screening Study (*Lancet* 2022)
7. TRICORDER AI Stethoscop) *Lancet* 2025
8. Pragmatic RCT of AI-ECG for Low LVEF (*BMC Medicine* 2025)
9. AI-enhanced ECG in Acute Cardiac Care, *Nature Med.* 2024
10. FLAVOUR II (*Lancet* 2025)

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Main flagship actions

Support for advanced therapies

Coordinate the development of centres of excellence with Member States

Life Sciences career development through Choose Europe

Attract and retain talent in synergy with Member States' activities.

Life Sciences Investors Interface

Connect startups, industry and investors.

Clinical Research Investment Plan

Facilitate funding for multi-country clinical trials.

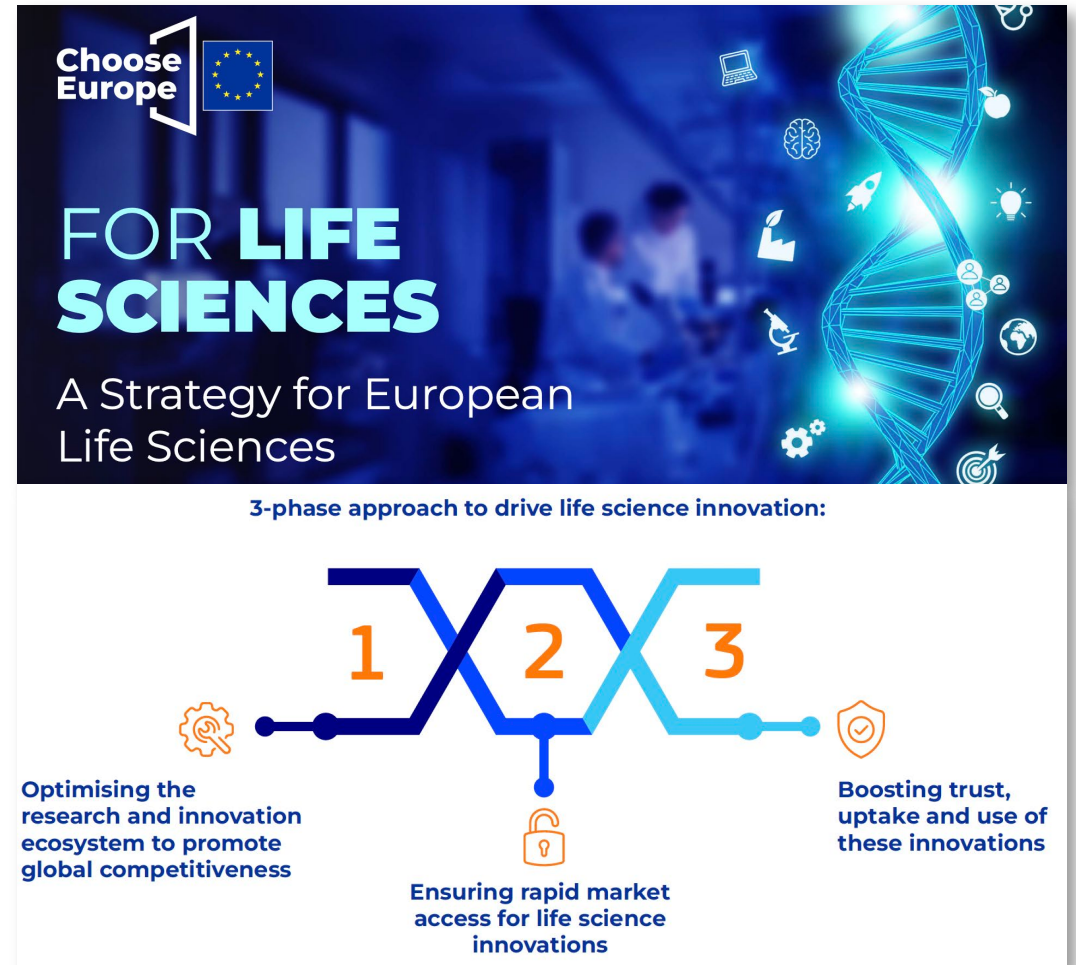
One-Health* Microbiome Initiative

Make the EU a world-class innovator in microbiome-based solutions.

EU Biotech Act

Foster innovation by simplifying rules and providing supportive measures.

* One Health recognises the interconnectedness of human, animal, and environmental health.



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Prevention

- Cardiometabolic Syndromes
- Nutrition & Soft drinks
- Nicotine
- Vaccination

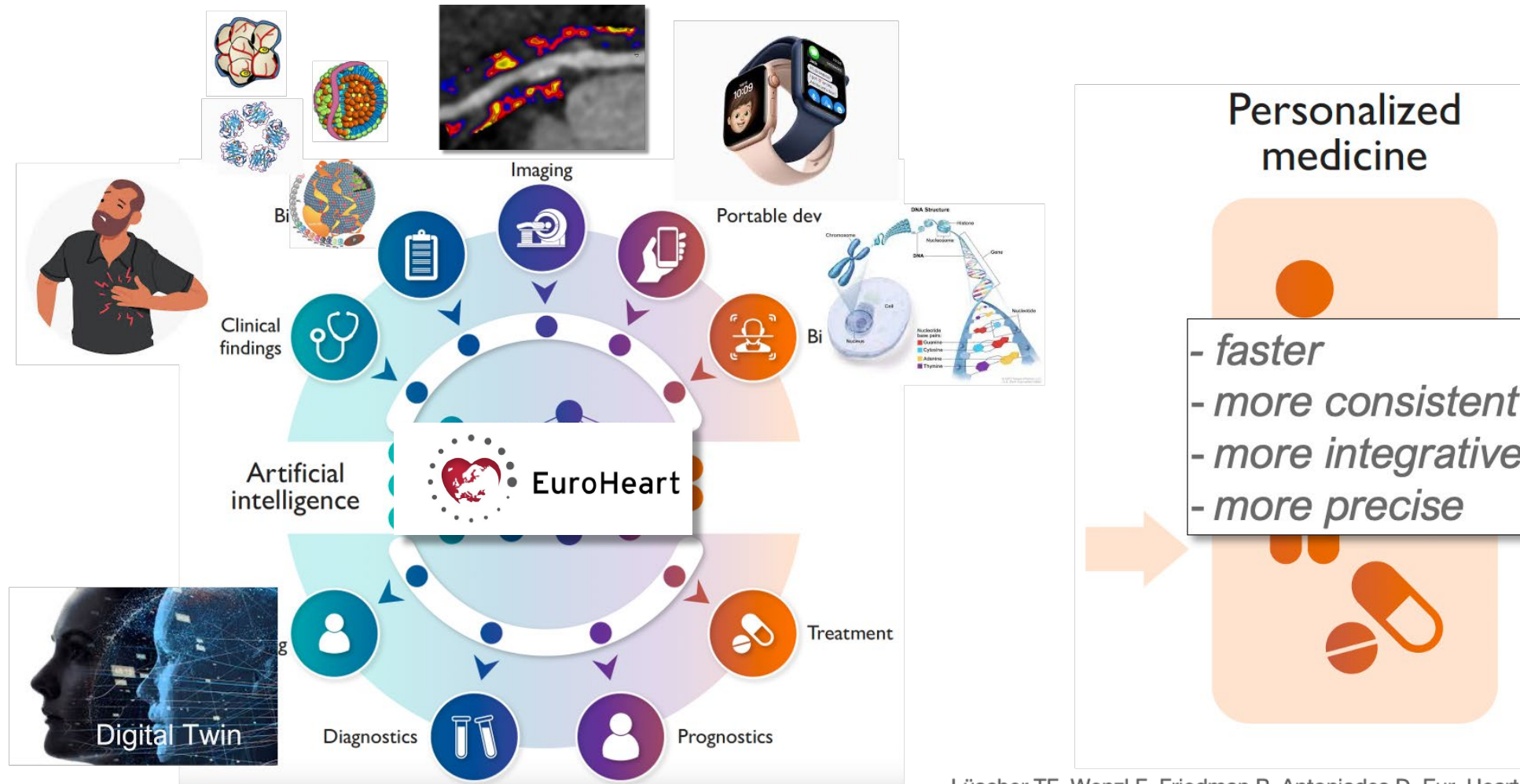
Artificial Intelligence

- Diagnostics
- Risk assessment
- Management

CV Research

- Closing the gap
- Unmet needs

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Lüscher TF, Wenzl F, Friedman P, Antoniadou D. Eur. Heart J. 2024; in press

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From an Impressive Legacy to a promising Outlook

- European CV Research and Medicine was highly successful
- Still, CVD are the major cause of mortality in Europe
- Unmet medical needs must be addressed
- Innovation must be fostered to compete with the US and China

Many thanks!

- The D
- Th EU
- property