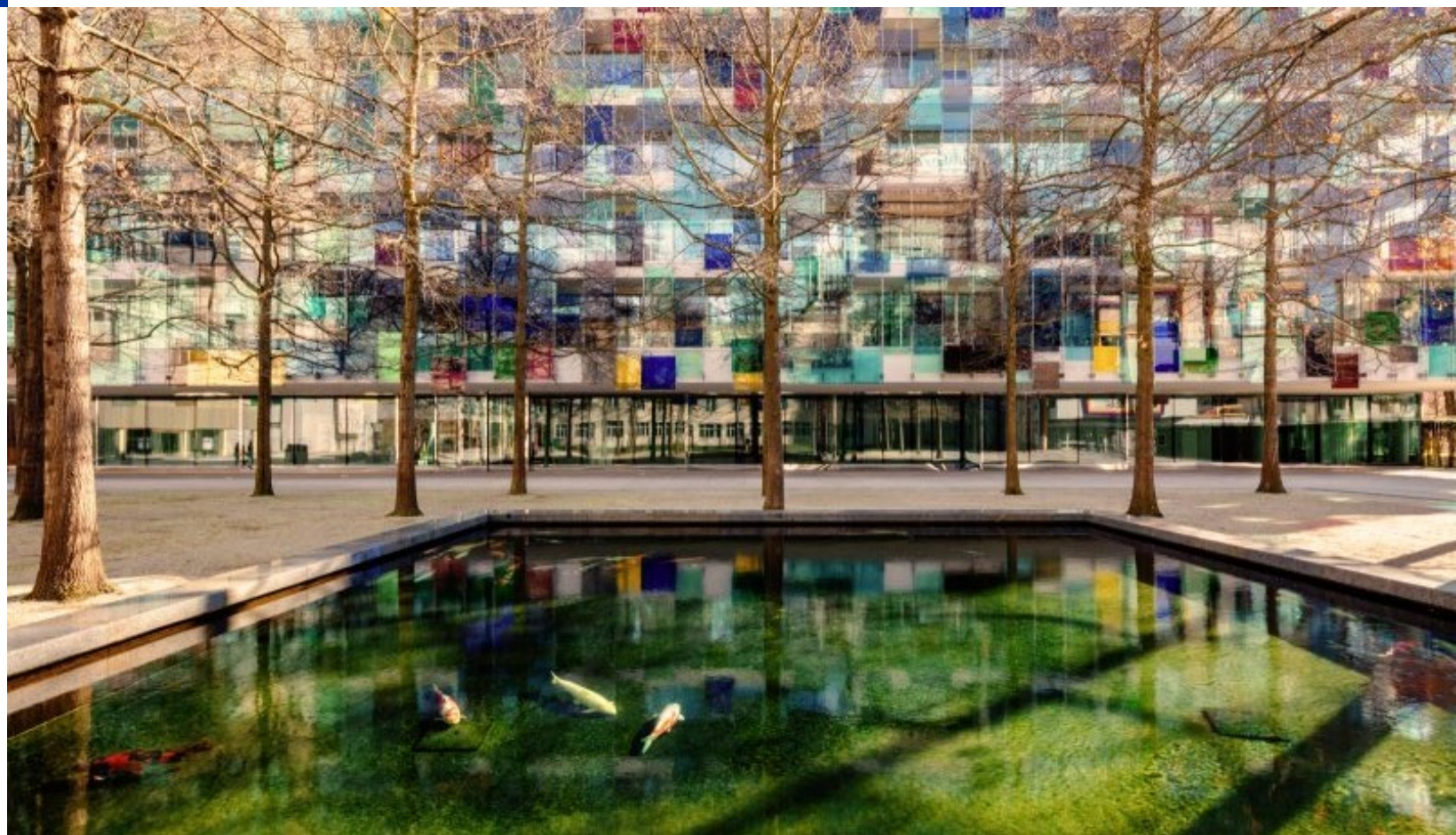


Karim Azer, PhD

Head Data & AI, Clinical Development, Novartis
Representing EFPIA

July 2nd, 2026

Fostering
innovation in
cardiovascular
diseases with
digitalisation and
AI



Agenda



01 Transformation opportunity of AI for CVD medicines



02 Smarter trials, better disease insights, accelerated impact for CVD patients



03 Making the future a reality



04 Stronger impact in multistakeholder collaboration

Despite available treatments, CVD is the #1 killer in EU and Globally, and burden is set to increase



1.7 million
deaths in the EU every year



62 million
people live impacted in the EU



€47 billion
in lost productivity



€ 282 billion
economic cost exceeds

Delayed Innovation to patients because of:

- **Rising timelines and size of CVOTs Driven by Declining Event Rates**
- **Limited predictive power of current ASCVD risk models**

Communication on an EU cardiovascular health plan: the Safe Hearts Plan

'The state of cardiovascular health in the EU' - Full Report: The State of Cardiovascular Health in the European Union | OECD.

From Breakthrough Science to Clinical Impact: How AI can Transform CVD Clinical Trials

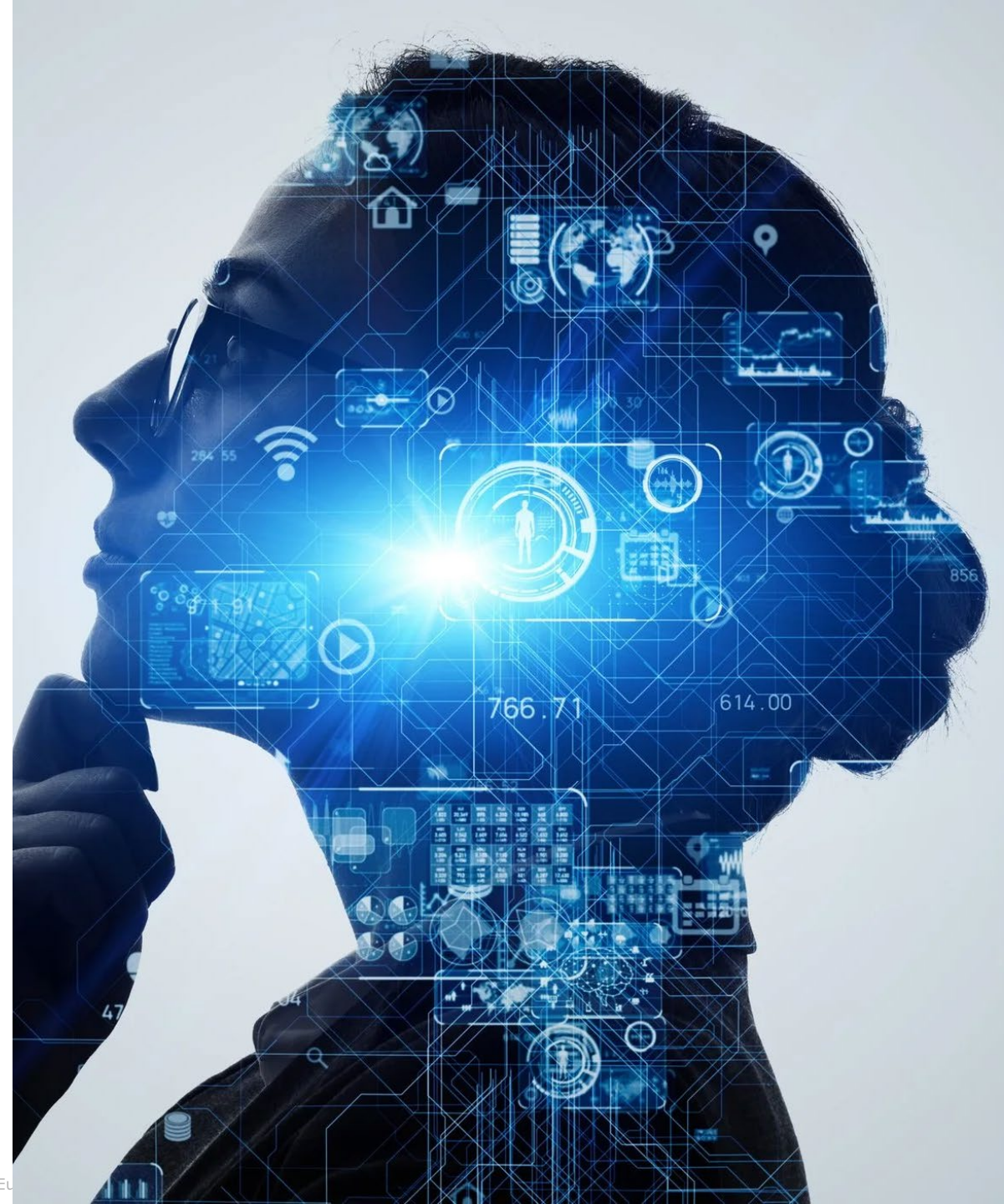
In 2024, two Nobel prizes underscored the potential of AI in transforming how we do science and develop drugs



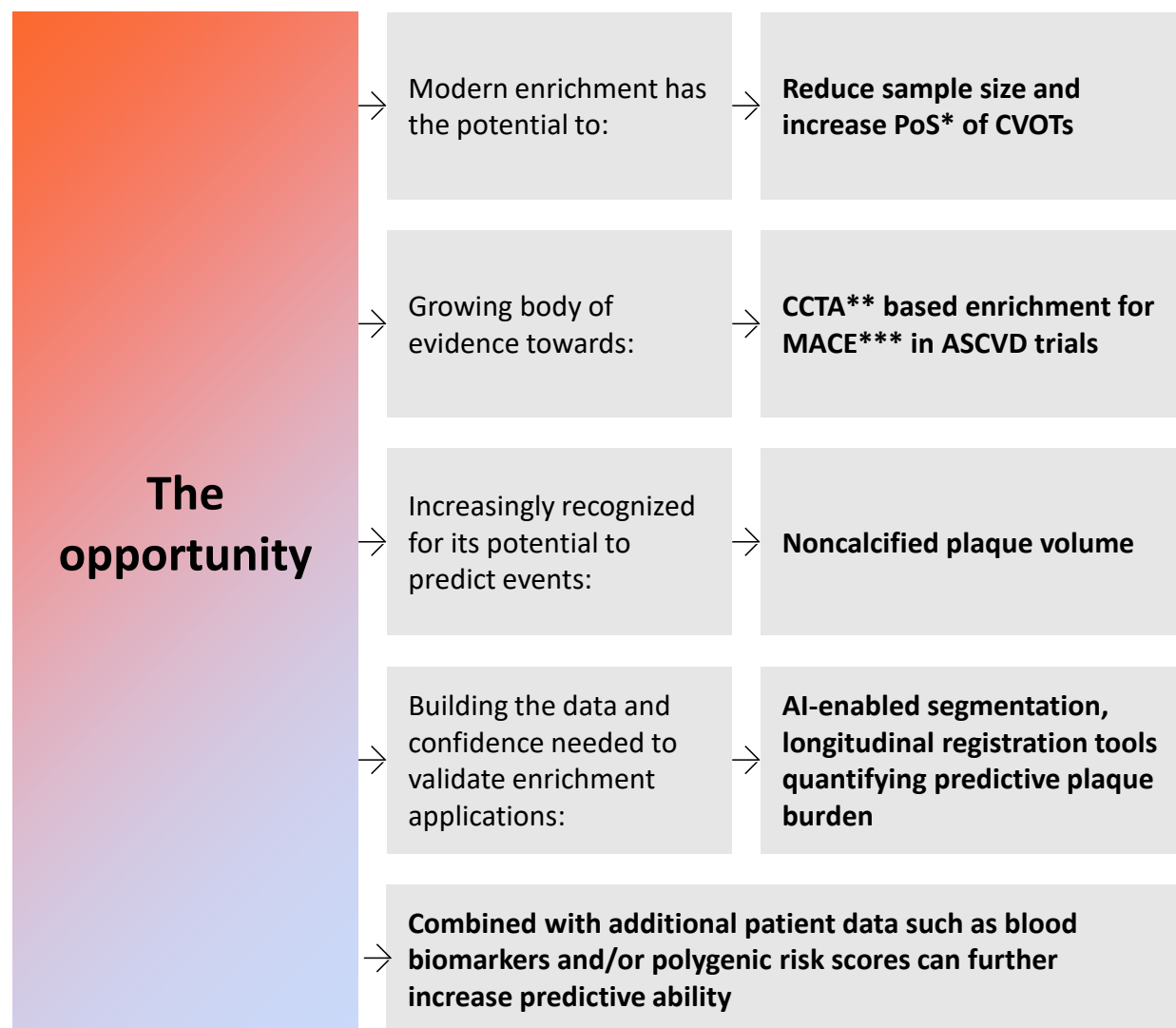
Patient-level, multi-modal data platforms combined with advanced AI enable faster, smarter cardiology trials by improving risk prediction, enrichment and endpoints



Advancing regulatory guidance and clarity on incorporation of AI in drug development and pathways for early engagement are key to successful implementation



Next-Generation AI-Enabled Enrichment for ASCVD Trials



*PoS – probability of success

**CCTA: Coronary Computed Tomography Angiography

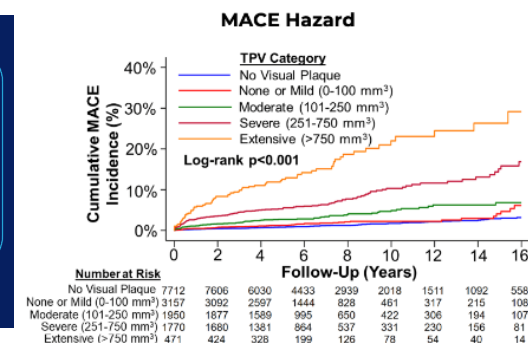
*** MACE: Major Adverse CV events

AI-Based Coronary Plaque Analysis and Adverse Cardiovascular Events: The Mass General Brigham CCTA Registry

Daniel M. Huck MD MPH¹, Arthur Shiyovich MD¹, Rhanderson Cardoso MD¹, Stephanie A. Besser MS¹, Brittany N. Weber MD PhD¹, Adam N. Berman MD, David W. Biery BS¹, Camila V. Blair, MD¹, Sumit Gupta MBBS PhD¹, Ayaz Aghayev MD¹, Michael Steigner MD¹, Jon Hainer BS¹, Michael Lu MD², Cian McCarthy MBChB BAO², Khurram Nasir MD MPH³, Campbell Rogers MD⁴, Sandeep Hedgire, MD², Marcelo F. Di Carli MD¹, Brian Ghoshhajra MD MBA², Ron Blankstein MD¹

1. Brigham and Women's Hospital, Harvard Medical School, Boston, MA
2. Massachusetts General Hospital, Harvard Medical School, Boston, MA
3. Houston Methodist, Houston, TX
4. Heartflow, Inc., Mountain View, CA

In a large CCTA registry, **AI-quantified coronary plaque volume** was associated with **adverse cardiovascular events** independent of traditional cardiovascular risk factors and stenosis severity



Reproduced with permission from
Journal of ACC VOL. 87, NO. 13, SUPPLA, 2026

Schulze et al. (Nature Reviews Cardiology, 2026)
Huck et al. (JACC, 2026)

Next-Generation AI-Enabled Enrichment for AF* Rhythm-Control Trials

Circulation: Arrhythmia and Electrophysiology



- Ubiquitous ECG data coupled with AI
 - regulatory-approved AI-SaMD models for risk prediction



- AI-SaMDs are predictive of recurrence of atrial fibrillation
 - hold the potential for use as enrichment tool in atrial fibrillation clinical trials



- Mounting clinical validation positions ECG-AI for prognostic enrichment
 - enabling better, smarter, faster Ph2/3 AF trials



- Opportunities include development of new endpoints such as AF burden and prediction of MACE events

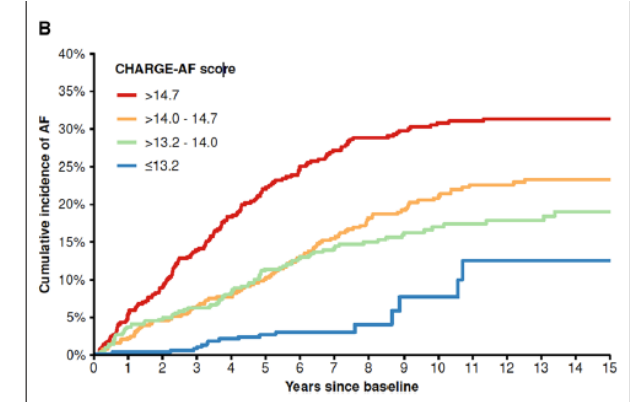
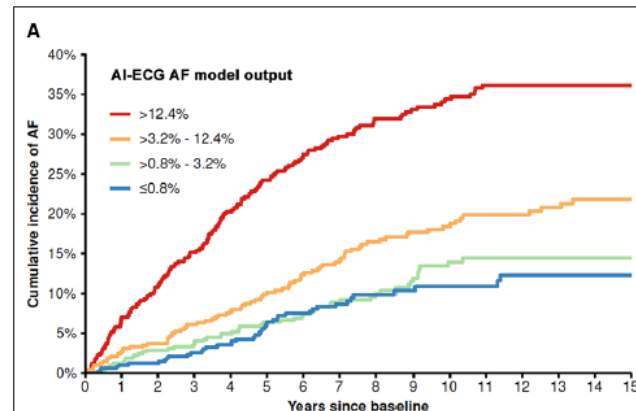
 **NOVARTIS** *AF – Atrial Fibrillation

ORIGINAL ARTICLE

Artificial Intelligence–Electrocardiography to Predict Incident Atrial Fibrillation

A Population-Based Study

Georgios Christopoulos, MD; Jonathan Graff-Radford , MD; Camden L. Lopez , MS; Xiaoxi Yao , PhD; Zach I. Attia , PhD; Alejandro A. Rabinstein , MD; Ronald C. Petersen, MD, PhD; David S. Knopman , MD; Michelle M. Mielke , PhD; Walter Kremers, PhD; Prashanthi Vemuri, PhD; Konstantinos C. Siontis , MD; Paul A. Friedman, MD; Peter A. Noseworthy , MD



European Heart Journal (2024) 45, 4291–4304
Circulation: Arrhythmia and Electrophysiology, Vol 13(12)
Nature Reviews | Cardiology volume 18 | July 2021

Reproduced with permission from *Circ Arrhythm Electrophysiol.* 2020;13:e009355

Classified as public by the European Medicines Agency

Accelerated Surrogate Endpoint Development leveraging Data & AI technology to support Conditional Approvals

CCTA & ECG Data +AI



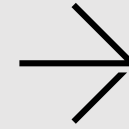
Have potential to enrich large CV trials—accelerating the right medicines to the right patients

Novel risk scores



AI in prospective trials and healthcare settings, multi-modal platforms integrating EHR, imaging, ECG, genetics, and outcomes help advancing toward surrogate endpoints for conditional approvals

Multimodal Data & AI

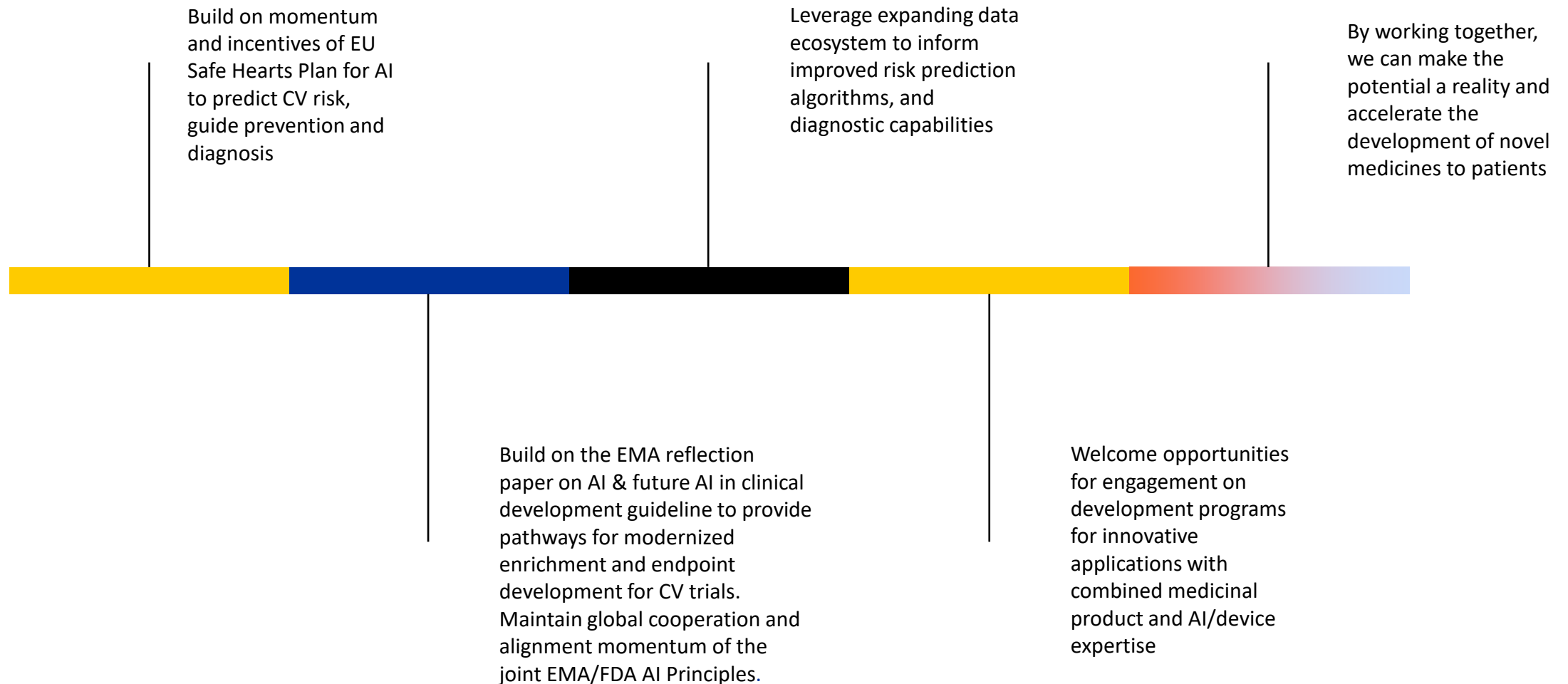


Availability of integrated multi-modal patient level data platforms and AI technology have significantly increased since LDL-C and BP as surrogate endpoints for ASCVD and hypertension approvals

Opportunity

To combine data from randomized control trials and external multi-modal data platforms to more rapidly develop surrogate endpoints, accelerate approvals, without compromising the evidence package

How do we achieve this future together, for patients?



A multistakeholder collaboration will enable the future vision



- Deep scientific expertise and design-based development and validation
 - Key to transforming and modernizing clinical development



- Continual regulatory advancement is an enabler
 - To deploy advanced tools as decision-making aids, bringing drugs to patients faster



- Investment and change management is necessary
 - To incorporate AI technology in large cardiovascular trials, to advance the right drug to the right patient



- In multistakeholder collaboration, the future can be re-imagined and the hope for patients ever brighter



Summary and Key Takeaways



CVD remains the #1 killer in EU and globally, and burden continues to increase



CV event rates are lower, increase size and timelines for CVOTs, delaying innovation to patients that need it most



AI technology coupled with data platforms offer the opportunity to support better, faster, smarter clinical trials and endpoints for conditional approvals in the EU



Continuing to advance the regulatory framework for modernizing cardiology drug development will set the pace for innovative medicines



Investment in science and technology, alongside multistakeholder collaboration, will usher in an AI-enabled future for patients

Thank you