Delivering Measurable Patient Outcomes with AI

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University of Edinburgh
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Introduction

Examples of AI in action with featured Roche solutions

Enablers and Closing Thoughts

Introduction: the value opportunity and our business

The healthcare challenges we face together

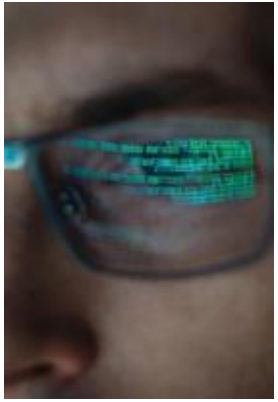
Healthcare systems | **Technology & Processes**

Aging population and rising disease burden of non-communicable diseases (NCDs)[1]

Increasing financial pressure [2]

Staffing shortages [3]

Opportunities for personalized care [4]



Growth of data to manage [5]

Rise of AI [3]

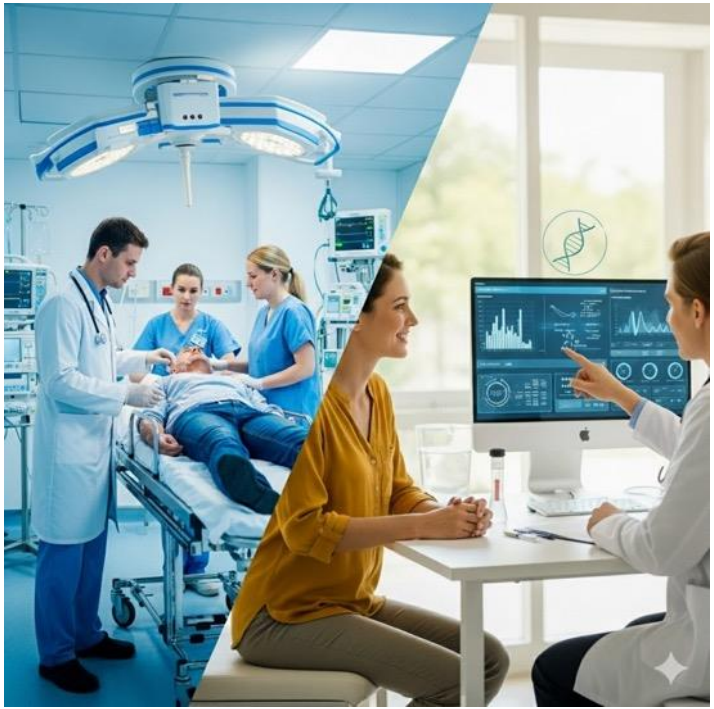
1. WHO. World Health Statistics 2023: Monitoring Health for the SDGs. [PDF Report; May, 2023] https://iris.who.int/bitstream/handle/10665/367912/9789240074323-eng.pdf?sequence=1 , accessed April 7, 2024
2. Navigating Financial Pressures in 2025 [Internet; Jan, 2025] .https://healthcareexecutive.org/sponsored-content/navigating-financial-pressures-in-2025 Aug 25, 2025
3. World Economic Forum. How AI can transform patient care and treatment [Internet; updated 2024 Jan 17; cited 2024 Mar 29]. https://www.weforum.org/agenda/2024/01/how-ai-can-transform-patient-care-and-treatment/, accessed April 6, 2024
4. Becker's Hospital Review. The Financial Pressure in Healthcare Systems [Internet; Feb, 2025] .https://www.researchandmarkets.com/reports/4655540/personalized-medicine-market-types accessed March 29, 2024
5. LEK. Tapping Into New Potential: Realising the Value of Data in the Healthcare Sector. https://www.lek.com/insights/hea/eu/ei/tapping-new-potential-realising-value-data-healthcare-sector, accessed March 25, 2024

RIS value opportunities and business segments

Patient-centricity and the digital health opportunity

Paradigm shifts from a reactive hospital-centric model to a predictive/preventative digital-first model

from traditional healthcare settings to remote patient monitoring and management



from reactive care to predictive analytics and preventative medicine

Examples: AI in action with featured Roche solutions

Predict & Prevent

Detect diseases early

AI opportunities

- Identify patients at risk
- Predict and diagnose disease early
- Improve chronic disease management
- Support clinical decisions

Featured Indications

Risk Stratification Algorithm:

- Colorectal Cancer (CRC)

Radiology and Sonography Solutions

- Breast Cancer
- Congenital Heart Defects

Colon cancer

The importance of early detection

Colorectal cancer is the second deadliest cancer worldwide for both sexes, with over 900,000 annual deaths and 1.9 million annual new cases.[1]

With a 5-year survival rate of 90% in **early stages**, detecting colorectal cancer early is crucial.[2]

1. Ferlay J, et al. Global Cancer Observatory: Colorectum [Internet; published 2024; cited 2025 July 10]. Available from: https://gco.iarc.who.int/media/globocan/factsheets/cancers/41-colorectum-fact-sheet.pdf.
2. Navarro M, et al. Colorectal cancer population screening programs worldwide in 2016: An update. World J Gastroenterol. 2017 May;23(20):3632-3642. DOI: 10.3748/wjg.v23.i20.3632.

Detect colon cancer early

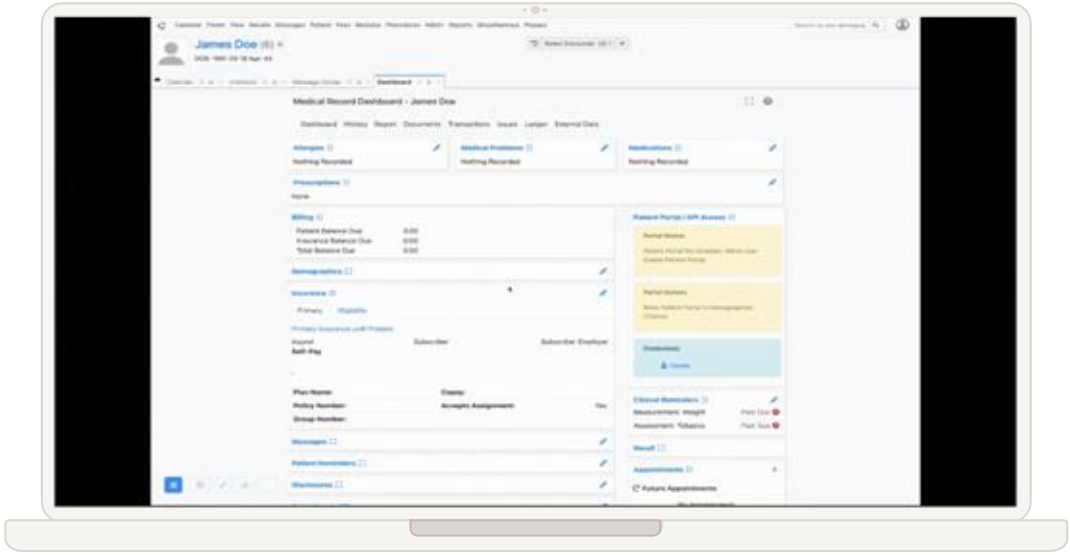
navify® Algorithm Suite LGI-Flag

Description:

LGI-Flag a machine learning based algorithm to aid in detection of patients who are at increased risk of harboring colorectal cancer (CRC)

Input parameters

- Complete Blood Count (CBC)[1]
- Age[1]
- Gender (at birth)[1]



Benefits:

- **8x more** CRC cases (all stages) detected in the flagged population compared with routine CRC colonoscopy screenings[2]
- **76%** of overdue patients agreed to undergo screening (following personalized outreach)[2]

1. Method Sheet LGI-Flag V1, reference: 09823387001.
2. Underberger D, et al. NEJM Catalyst. 2022;3(4). doi: 10.1056/CAT.21.0170

AI-augmented imaging workflows in screening

Significant quantifiable benefits for patients and healthcare providers

https://www.nature.com/articles/s43018-026-01126-1
https://reports.mountsinai.org/article/obgyn2026-7_ai-heart-imaging

Evidence of benefits in breast cancer screening:

- >10% increased **cancer detection rates**
- **Workload relief** for radiologists
- ~80% reduction in **waiting times** for patients to receive their results

Evidence of benefits foetal screenings for congenital heart defects:

- Improved **detection rates** of ultrasound suspicious defects to more than 97%
- 18% reduction in **reading time**
- 19% improvement in **confidence score**

"This technology allows for 'levelling' of the field of prenatal diagnosis to offer close to expert-level review of foetal ultrasounds, particularly in centres or geographical locations without foetal heart experts."

Informed Clinician

Drive operational efficiency

AI opportunities

- Automate administrative tasks
- Support decision making for HCPs
- Improve lab staff efficiency

Featured solution

navify® Clinical Hub

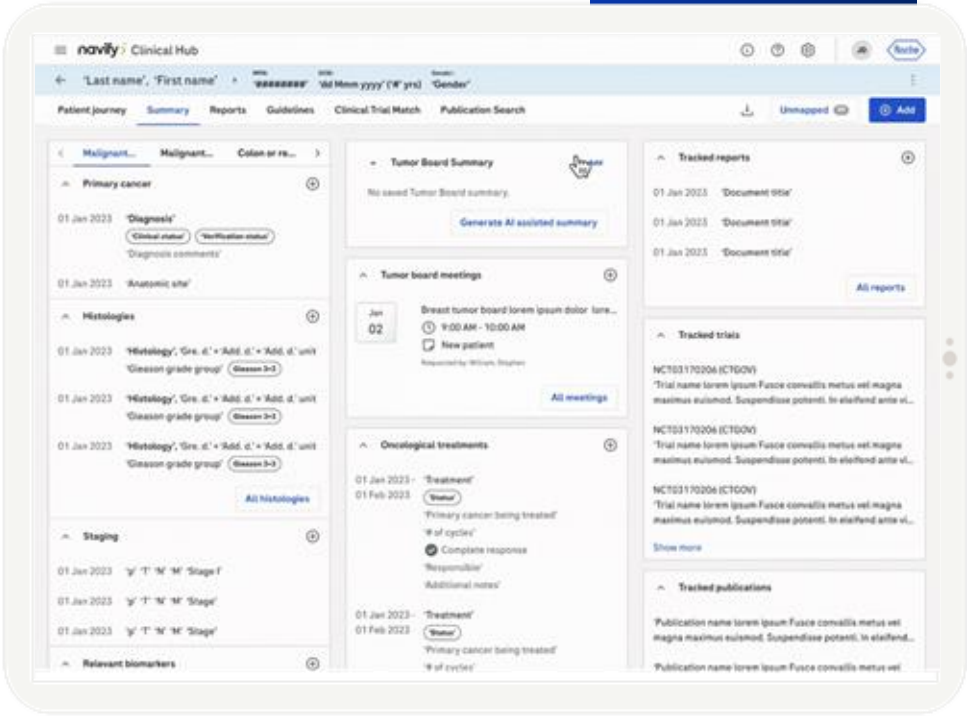
LLMs reduce case summarization time by **40-50% (approx. 11.25 hours/week/team)** [1]

1 Case Study Northside Hospital, navify® Clinical Hub for Oncology -AI summary capability. Individual lab results may vary, and testimonials are not claimed to represent typical results.
*In development, not commercially available.

Save time on oncology notes summarization

navify® Clinical hub

4/5 Overall effectiveness



Description

navify® Clinical hub is a workflow solution that empowers multidisciplinary care teams to review, align and decide on the optimal treatment for the patient

LLMs help HCPs prepare summaries before tumor boards and ease this administrative burden.

Value

40-50% reduction in case summarization time

11.25 hours saved per week [1]

1 Case Study Northside Hospital, navify® Clinical Hub for Oncology -AI summary capability. Individual lab results may vary, and testimonials are not claimed to represent typical results.

AI-powered digital pathology diagnostic algorithms

Pathologists can make confident decisions based on quick, accurate analysis, with up to 67% time saving[1]

HER2 image analysis breast algorithm is an adjunctive computer-assisted tool that identifies HER2 positive tumor cell membrane within a pathologist-annotated viable tumor region.

PD-L1 image analysis NSCLC algorithm is an adjunctive computer-assisted tool that identifies PD-L1 positive and negative tumor cells within a pathologist-annotated viable tumor region.

https://diagnostics.roche.com/global/en/products/product-category/lab-type/pathology-lab/digital-pathology/image-analysis-algorithms.html

1. Gough, M. et al. Improved concordance of challenging human epidermal growth factor receptor 2 dual in-situ hybridisation cases with the use of a digital image analysis algorithm in breast cancer. Histopathology. 2023 Jun 23; 83:647-656.

Personalized & Remote

Empowering patients with tailored care

AI opportunities

- Patients take control of their health
- Manage conditions from home
- Finding best treatment for each person

Featured solutions

Accu-Chek Smart Guide

AI-enabled predictive algorithms assess the risk of **hypoglycemia within the next 30 minutes**, continuously forecast glucose trends over the next two hours, and **estimate nocturnal hypoglycemia risk** [1]

1. Glatzer T, Ehrmann D, Gehr B, et al. Clinical usage and potential benefits of a continuous glucose monitoring predict app. J Diabetes Sci Technol. 2024. Epub ahead of print.
2. Roche algorithms are CE-IVD marked. For Research Use Only in the US, not for use in diagnostic procedures. Refer to the product-specific labeling for the regulatory status of algorithms.

Life of patients with diabetes, made simpler

mySugr Glucose Insights *

Description

mySugr Glucose Insights uses AI to predict blood glucose levels with the goal to empower patients with a CGM sensor to act before glucose excursions happen.

Features

- Real-time glucose readings
- 30m hypo warning 2hr glucose prediction
- 7h nocturnal hypoglycemia prediction
- Glucose patterns detection

Key gains from the transition to mySugr

- **One sensor, one app:** patients no longer need to toggle between two apps, all features in a single app to improve customer experience.
- **Infinite scrolling for historical data insight:** Patients can seamlessly review past glucose trends
- **Meal pictures:** visual nutrition tracking enabled for more accurate data insights
- **Integration with Apple/Google Health:** fitness and health metrics centralized for a 360-degree view

*Global launch starting in Q4/2025

Roche Is Transforming Diabetes Management with AI

Nominated for the 2026 AI Impact Award in the Product and Customer Experience category

https://www.porsche-consulting.com/international/en/article/roche-transforming-diabetes-management-ai

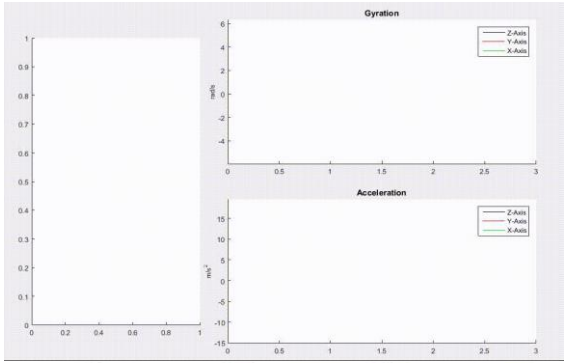
Digital Biomarkers

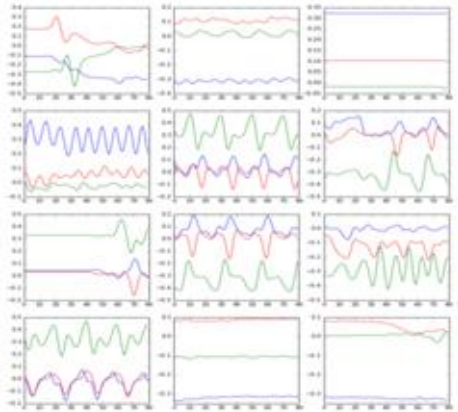
Providing enhanced patient insights and novel endpoints in clinical trials

- More **sensitive, precise** and **objective** measurement
- **Continuous** and **longitudinal** measurement captures episodic and rare events
- **Reduced burden** of assessment
- Greater **real-world relevance** through data collection in daily living
- **Adherence** can be driven through gamification and monitored directly in real-time
- **Complements**, and can be correlated directly with, traditional clinical assessment and PROs

Continuous passive monitoring

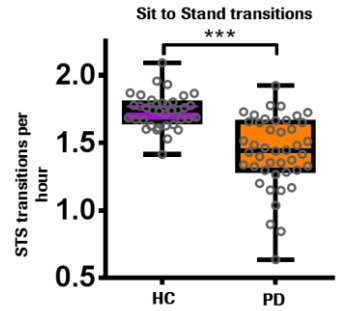
AI classification of activity and performance in daily tasks

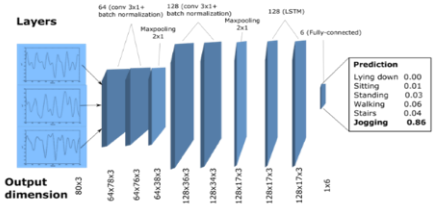




Parkinson's disease

PASADENA
BP39529

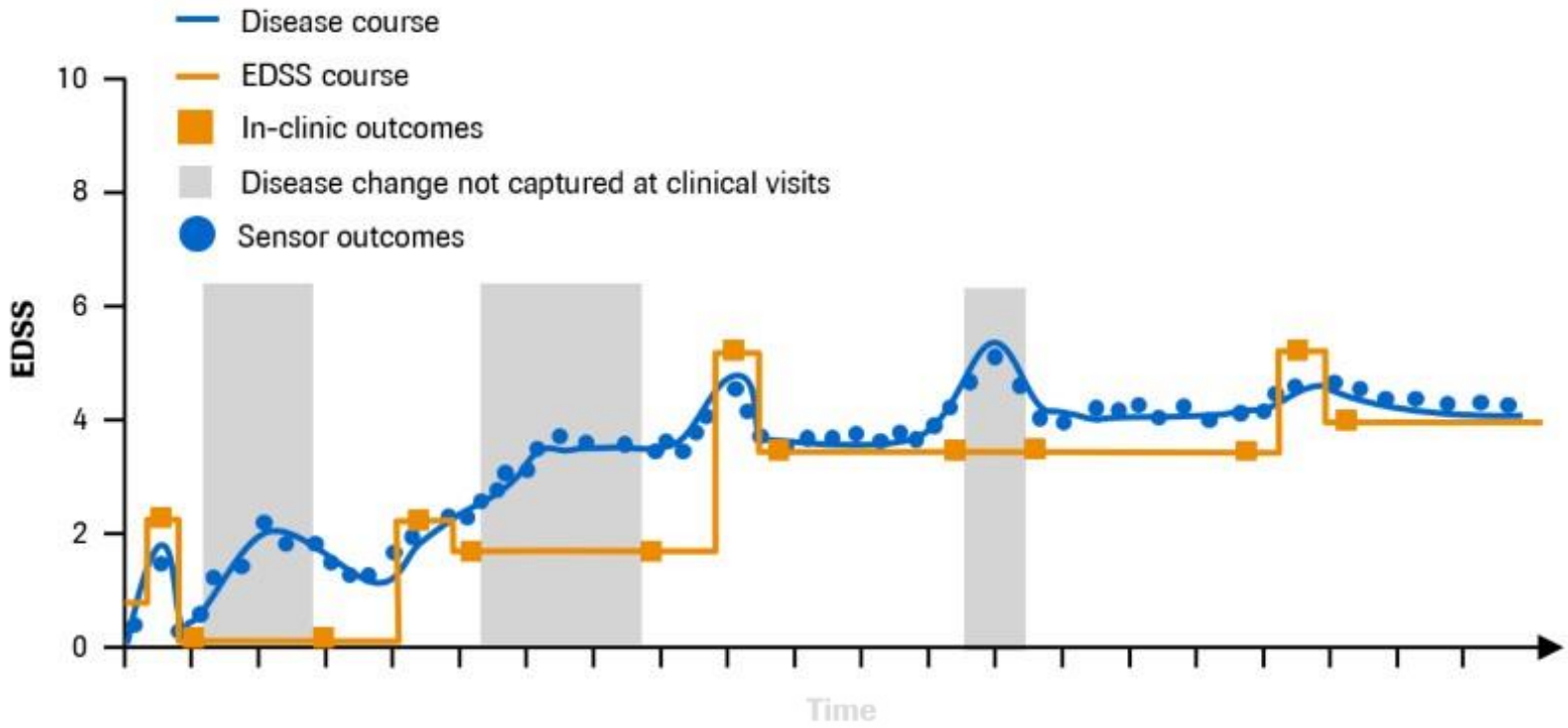




Human Activity Recognition (HAR)

Digital Biomarkers in Multiple Sclerosis

Sensitive detection of subclinical disease activity



M Baker, J van Beek & C Gossens: https://www.nature.com/articles/d42473-019-00412-0

Digital biomarker solutions in PD and HD deliver significant value

Accelerating timelines, whilst reducing costs and patient burden

Study duration halved[2]

70-80% sample size reduction[1]

>60% overall cost reduction[2]

[1]

A digital motor score for sensitive detection of progression in Huntington's disease

Louis-Solal Giboin, et al.

Brain, Volume 148, Issue 9, September 2025, Pages 3228 3238
https://doi.org/10.1093/brain/awaf127

"Simulated sample size calculations demonstrated that using the HDDMS instead of the cUHDRS can substantially reduce the sample size (by 75%–80%) required to detect a 40% effect size difference in people with HD-ISS Stage 2 or Stage 3 while still maintaining a statistical power of 0.8 of the planned study"

[2] Digital Health Lab Day 2024 -The role of digital biomarkers in evidence generation – development, use and value (Guy Bogaarts)

Enablers and Closing Thoughts

FAIR Data Principles

A critical enabler for digital solutions and AI

Findable

- digitised, online
- indexed

Accessible

- entitlements, consent, privacy, etc.
- APIs

Interoperable

- technical standards
- semantics

Reuseable

- curated for context
- ethics, consent, privacy, etc.

Source: https://www.biomeris.it/en/introduction-fair-principles/

Digital Sovereignty

Rewiring Global Tech

Why Nations Mandate Control?

- **National Security:** Safeguarding critical public infrastructure against foreign reconnaissance and extraterritorial access.
- **Economic Autonomy:** Preventing vendor monopolies while fostering indigenous tech, AI models, and local computing capital.
- **Jurisdictional Shield:** Neutralizing conflicting cross-border warrants like the US CLOUD Act and foreign espionage statutes.

The AI Sovereignty Frontier

- **Foundation Models:** Auditable datasets free from foreign jurisdiction liabilities, state subsidies driving regional foundational LLMs, curating linguistic nuances and regional policy norms, etc.
- **Inference & Workloads:** In-country processing with zero prompt egress outside national borders, hardware enclaves isolating customer weights during execution, on-premise sovereign instances for critical infrastructure.

Digital Sovereignty

Key Global Frameworks

Jurisdiction	Major Frameworks	Core Mandate
EU	EU AI Act, Data Act, NIS2, DORA	Extraterritorial AI guardrails, strict residency, cloud switching
USA	Executive Orders on AI, EAR Export Controls	Hardware containment, advanced GPU choke points, IaaS tracking
China	Data Security Law, Generative AI Measures	Complete domestic residency, mandatory algorithm registration
APAC & MEA	India DPDP, KSA Personal Data Protection Law	Cross-border whitelisting, sector-specific in-country compute

Digital Sovereignty

Key Global Frameworks

EU Cloud Sovereignty Framework: Developed by the European Commission, evaluates sovereign cloud providers using the **Sovereignty Effectiveness Assurance Level (SEAL)** model tiers:

- *SEAL-0:* No sovereignty
- *SEAL-1:* Jurisdictional sovereignty
- *SEAL-2:* Data sovereignty
- *SEAL-3:* Technological autonomy
- *SEAL-4:* Full sovereignty

Navigating the Regulatory Landscape

Such as the EU AI Act

What the EU AI Act means for healthcare?

- Medical Device Software (MDSW) is generally classified as a **high-risk AI system**, demanding top safety standards.*
- The Act **mandates stringent requirements**: data quality, transparency, human oversight, cybersecurity.
- The Act demands rigorous **pre-market assessment** and continuous **post-market monitoring**

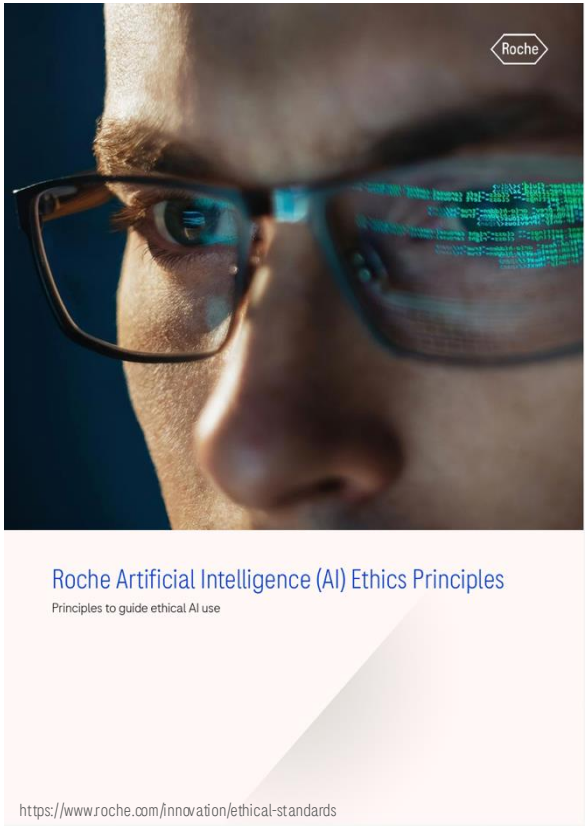
Roche's Ethical AI Principles

Ethical Use
Transparency
Explainability
Human Control
Empowering People
Accountability
Fairness & Justice
Privacy
Security
Safety by Design
Sustainability

*AI products that are medical devices or IVDs (in vitro diagnostic medical devices) that need Notified Body involvement are automatically classified as high-risk.

AI Ethics

Roche is committed to ethical and trustworthy AI

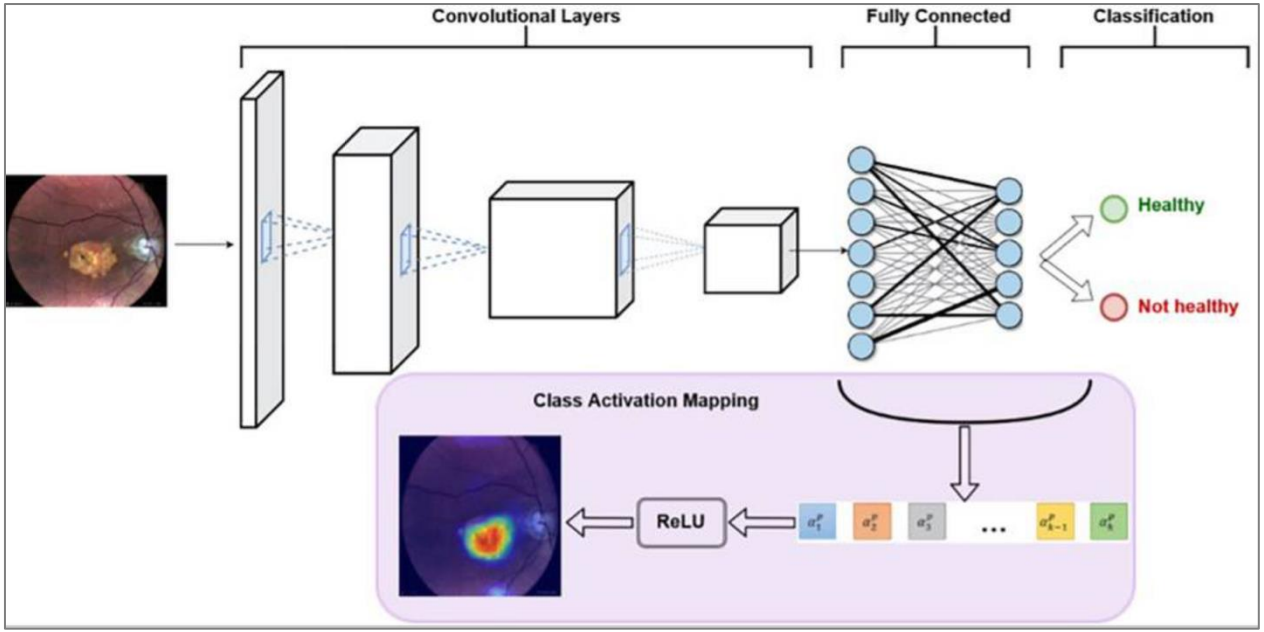


- Ethical Use
- Transparency
- **Explainability**
- Human Control
- Empowering People
- Accountability
- Fairness & Justice
- Privacy
- Security
- Safety by Design
- Sustainability

The ability of humans to understand and interpret AI solutions Roche aims for processes and methods that allow users to understand, interpret, and trust our AI solutions, allowing them to exercise meaningful control.

Explainability

Attribution mapping to visualize model attention on original medical images



An example from retinal imaging[1]

In addition to the feature extractor for classification of healthy vs geographic atrophy, a class activation map (CAM) module is employed to elucidate the interpreted outcomes and render a heatmap on the original retinal image.

(ReLU, rectified linear unit)

1. Valentina Sarao, et al. Explainable artificial intelligence model for the detection of geographic atrophy using colour retinal photographs, BMJ Open Ophthalmol. 2023 Dec 6;8(1):e001411. doi: 10.1136/bmjophth-2023-001411

Explainability

Polygenic risk scores: from black-box to explainable

arXiv > cs > arXiv:2604.08217

Search... Help | Ad

Computer Science > Computers and Society

[Submitted on 9 Apr 2026]

Co-design for Trustworthy AI: An Interpretable and Explainable Tool for Type 2 Diabetes Prediction Using Genomic Polygenic Risk Scores

Ralf Beuthan, Megan Coffee, Heejin Kim, Na Yeon Kim, Pedro Kringen, Elisabeth Hildt, Haekyung Lee, Seunggeun Lee, Emilie Wiinblad Mathez, Sira Maliphol, Vadim Pak, Yuna Park, Stephan Sonnenberg, Jesmin Jahan Tithi, Magnus Westerlund, Roberto V. Zicari

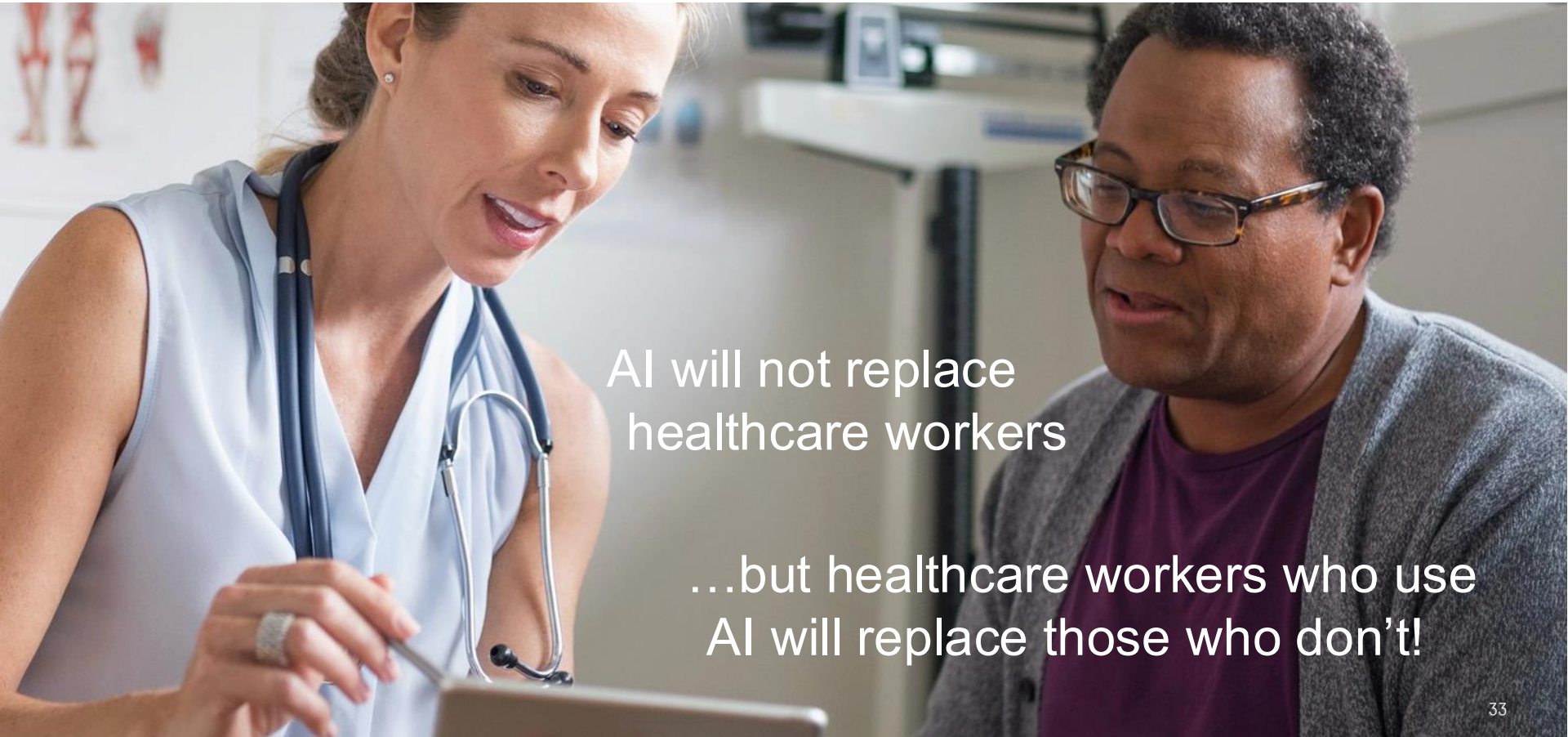
The polygenic risk scores (PRS) have emerged as an important methodology for quantifying genetic predisposition to complex traits and clinical disease. Significant progress has been made in applying PRS to conditions such as obesity, cancer, and type 2 diabetes (T2DM). Studies have demonstrated that PRS can effectively identify individuals at high risk, thereby enabling early screening, personalized treatment, and targeted interventions for diseases with a genetic predisposition. One current limitation of PRS, however, is the lack of interpretability tools. To address this problem for T2DM, researchers at the Graduate School of Data Science at the Seoul National University introduced eXplainable PRS (XPRS). This visualization tool decomposes PRSs into gene-level and single-nucleotide polymorphism (SNP) contribution scores via Shapley Additive Explanations (SHAP), providing granular insights into the specific genetic factors driving an individual's risk profile. We used a co-design approach to assess XPRS trustworthiness by considering legal, medical, ethical, and technical robustness during early design and potential clinical use. For that, we used Z-inspection, an ethically aligned Trustworthy AI co-design methodology, and piloted the Council of Europe's Human Rights, Democracy, and the Rule of Law Impact Assessment for AI Systems (HUDERIA) (Council of Europe (CAI) 2025). The findings of this use-case comprise a comprehensive set of ethical, legal, and technical lessons learned. These insights, identified by a multidisciplinary team of experts (ethics, legal, human rights, computer science, and medical), serve as a framework for designers to navigate future challenges with this and other AI systems. The findings also provide a useful reference for researchers developing explainability frameworks for PRS in diverse clinical contexts.

Visualisation of genetic risk scores to the level of individual genes and SNPs, using SHAP values, making the genetic drivers of an individual's risk profile visible and interpretable.

Applying Z-Inspection® co-design methodology to assess ethical, legal, medical, and technical dimensions, piloting the Council of Europe's HUDERIA framework.

"This is what responsible AI development looks like in practice: interdisciplinary, rigorous, grounded in real clinical stakes, and built on co-design from day one." [prof. Roberto Zicari]

SHAP (SHapley Additive exPlanations) values are a game-theoretic approach used to explain the output of any machine learning model. They break down a prediction by measuring the exact marginal contribution that each feature makes to the final result, allowing data scientists to see exactly how individual variables influence outcomes


AI will not replace
healthcare workers
…but healthcare workers who use
AI will replace those who don’t!

Doing now what patients need next