

Prevention of Cardiovascular Disease (CVD)

Detecting CVD risk early so it can
be prevented

Final Results 2025

June 2026



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Introduction

GENinCode

Genetic testing Company specialising in prevention of cardiovascular disease ('CVD') and risk of ovarian cancer

Revenue scale-up and expansion. Business transitioning to break-even over the medium-term. Labs and online systems operating in UK, US and EU

Test products: CE marked, US CLIA and CAP approved. FDA 'De Novo' filing for CARDIO inCode ongoing.

Established in 2007 with major investment in technology development and IT systems.

Substantial evidence base: Published clinical studies on >150,000 patients over 15 years supporting clinical adoption and regulatory pathway.

IP-protected tests focused on predictive and preventive care, improving patient outcome and reduced costs of treating CVD for healthcare systems.

Multiple test products complementary to CVD for lipid diagnosis and thrombotic risk.



Indiana
School of Medicine



Market



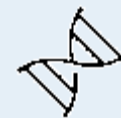
Cardiovascular disease ('CVD') **is the leading cause of death worldwide**



Over 17.9M deaths annually from CVD, accounting for c.31% of all deaths globally



Global annual cost of CVD to reach >\$1.04Tn by 2030



Unmet need to accelerate genetics in CVD as additive to current standard of care to improve risk assessment and prevent CVD



Global standard of care for assessing CVD requires update to include genetics and enable a step change in predicting the onset, risk assessment and improved treatment of CVD































Operational Highlights

- **Revenue growth** - Revenues increased 14% to £3.1m, (2024: £2.7m) driven by volume growth in US and EU.
- **FDA** - CARDIO inCode-Score 'De Novo' Supervisory Review completed. Discussions with FDA extended to confirm agreement of current ongoing program to resolve the outstanding deficiencies. Submission of New *De Novo* PMA expected during Q3 2026.
- **Thermo Fisher** - Collaboration to manufacture and distribute CARDIO inCode test through its lab network in US and EMEA.
- **US Sales** - Increasing commercial sales of LIPID inCode and CARDIO inCode. Over 40 clinics and institutions onboarded.
- **New York State Department of Health** - Clinical approval of CARDIO inCode (Dec 2025).
- **Reimbursement** - Inclusion of CARDIO inCode in 2025 US clinical lab fee schedule (Avg price \$500/test).
- **Growth of LIPID inCode:**
 - NHS expansion in North of England - headwinds from major strategic, organisational and funding changes across the NHS.
 - Additional growth of University Clinic Dresden, Germany for primary care diagnosis and growth of LIPID inCode® and THROMBO inCode® in Spain and Italy.
- **Spanish regions** - CARDIO inCode-Score pilots progressing in Extremadura with preparation of pilot publication in Catalonia.
- **ROCA** - Announcement of first ROCA commercial contract with NHS (UCLH). Ongoing contractual discussions with other NHS trusts

Financial highlights

- Revenues increased 14% to £3.1m, (2024: £2.7m) driven by volume growth in US and EU.
- Despite margins improving to 59% (2024: 53%), adjusted EBITDA loss was (£4.9m) (2024: loss of (£4.4m)) reflecting increased commercial support and reduced 2025 annual R&D tax credit.
- Cash reserves of £0.8m at 31 December 2025 (2024: £1.1m). £4.7m (Gross) secondary placing completed in March 2026.

Product Portfolio: Cardiovascular Disease (CVD)

		 CAP ACCREDITED CLIA certified	 FDA	 CE UK CA	 CE
	Assessment of the coronary genetic risk and CVD risk stratification	 			 *
	Diagnosis and management of hypercholesterolemia				
	Diagnosis and management of genetic thrombophilia and thrombosis risk	 Q4 2026			
	Diagnosis of the cause of sudden cardiac death and familial heart disease	 Q1 2027	 Q1 2027		 * *
	Early detection of familial ovarian cancer	 Est 2027			

* AEMPS - Spain

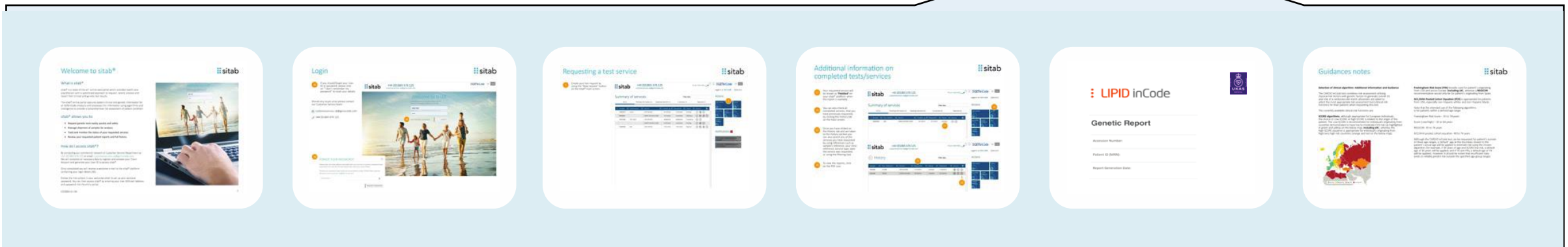
** Sudd inCode EU clinical lab services under ISO15189

International Online Reporting – SITAB (System of Integrated Traceability, Analysis and Biology)



SITAB Bioinformatics and Online Reporting Tool

SITAB online international system, AI risk scores, data warehousing and reporting



Cardiovascular Disease is the Leading Cause of Death Worldwide¹

In the US

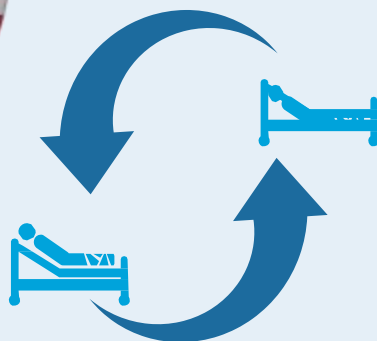


83M Americans living with CVD²
(Set to rise to 131M over next two decades)⁴



One in every three deaths, 919,000 deaths/year³

805,000 heart attacks a year in the US
605,000 first heart attack
200,000 recurrent attacks



\$407Bn
Estimated annual direct and indirect cost of CVD and stroke to US hospitals and lost productivity over **\$351Bn** annually in 2014-15. (Set to rise to **\$818Bn** by 2030)⁵

Global cost of CVD⁶

2020	2030
\$	\$
\$957Bn	\$1.04Tn

1. WHO – 2024 : CVD leading cause of mortality

2. <https://www.ncbi.nlm.nih.gov/books/NBK83160/#~:text=The%20AHA%20reports%20that%20approximately,et%20al.%2C%202010>.

3. www.cdc.gov/mcd.html - National Center for Health Statistics. Multiple causes of death 2018-2023 on CDC Wonder database.

4. Science News: Cardiovascular Disease costs will exceed \$1 Trillion by 2035: February 14 2017

5. www.acc.org AHA 2019 AHA Heart Disease and Stroke: Stats & www.ahajournals.org/doi/10.1161/CIR.0000000000001258

6. World Heart Federation – Champion Advocates Programme – 2024 <https://world-heart-federation.org/wp-content/uploads/2021/04/Infographic-Why-Circulatory-Health-Matters.pdf>

US Strategy: CARDIO inCode and LIPID inCode



Overview:

- Polygenic 'lifetime risk' scores for prevention of Cardiovascular Disease
- Commercial onboarding of KOL US Institutions
- Growing demand and profile for LIPID inCode and CARDIO inCode PRS tests
- US revenue including insurance claims and self-pay



Regulatory:

- CAP and CMS CLIA certification US Inc laboratory in Irvine, California.
- FDA 'De Novo' approval discussions ongoing for CARDIO inCode-Score



Reimbursement:

- LIPID inCode reimbursement CPT codes and insurance cover increasing
- CARDIO inCode CPT PLA coding (0401U) approved by American Medical Association.
- CARDIO inCode pricing in CMS 2025 Clinical Lab Fee Schedule ~Median US\$500 test*
- MoIDx submission for US state-based reimbursement in preparation post FDA approval



Commercial:

- KOL focus, education and SITAB portal onboarding
- Commercial Payer Discussions progressing benefits investigation and 'out of network' payer coverage
- Service based testing across institutions, community clinics and executive health
- Commercial collaborations – Thermo Fisher, US labs

CLFS state pricing ranges from \$450-\$570/test

CAD PRS in ACC/AHA guidelines (Mar 2026)

The updated ACC/AHA guidelines recommend use of CAD PRS as a new 'risk enhancer' to improve **Calculation, Personalization & Reclassification of CAD risk – 'CPR'** in adults 30-70 Years.

CAD PRS enables 'earlier in life' risk assessment and prevention through:

- **Risk Reclassification**

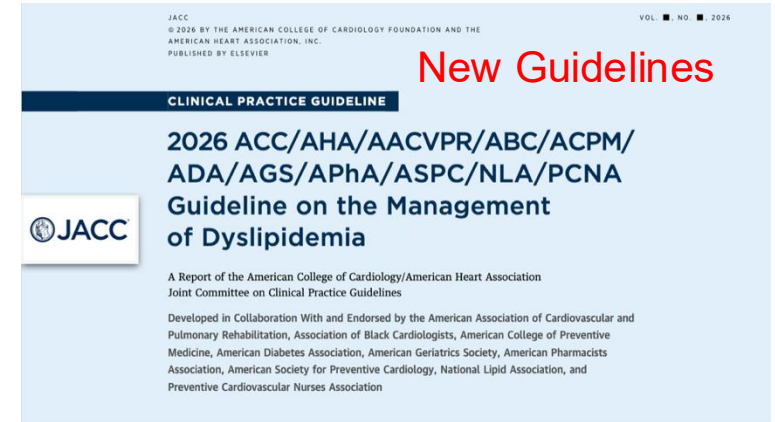
Helps to reclassify individuals at borderline or intermediate clinical risk by identifying those who may be under diagnosed by standard clinical risk assessment tools.

- **Younger Adult lifetime risk assessment**

Helps identify individuals at higher lifetime risk who may need earlier lifestyle and/or pharmacological intervention e.g. statin treatment to reduce cholesterol at a younger age.

- **Family History application**

CAD PRS is particularly useful for assessing individuals with limited family history or those with a low clinical risk but a strong family history of premature CAD, as the CAD PRS risk is additive to family history.



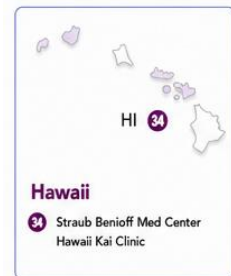
US Client Map: 70+ active ordering sites (May 2026)

California

- 1 Beverly Hills Cardiovascular
- 2 Advanced Cardiology Medical Associates
- 3 Mission Heritage Mission Viejo
- 4 California Heart Associates
- 5 Cardiology Consultants of Santa Monica
- 6 Cardiovascular Consultants Medical Group - Encino
- 7 Cardiovascular Consultants Medical Group - Santa Clarita
- 8 Cardiovascular Institute of San Diego
- 9 Dr Ali Health and Wellness
- 10 Franklin Lowe MD
- 11 Kaiser Permanente
- 12 Lyle D Kurtz, MD
- 13 Maggie Boomgaarden, ND
- 14 National Heart Institute
- 15 Pacific Heart
- 16 San Diego Cardiac Center
- 17 Simonini Cardiology
- 18 UC San Diego Health
- 19 UCI - Susan Samueli
- 20 Integrative Health Institute
- 20 UCI Health Newport Beach

Arizona

- 21 Banner Health - Cardiology
- 22 Malin Medical
- 23 Cardiovascular & Heart Failure Center
- 24 Cardiovascular Associates of Mesa
- 25 Tucson Community Pediatric Specialists
- 26 Essential Family Health
- 27 Scottsdale Private Physicians



Colorado

- 31 Advanced Heart & Vein Center - Rose/Denver/Thornton
- 32 Colorado Springs Cardiology
- 33 Russak Personalized Medicine

Texas

- 50 Baylor Medical Center - Cardiology
- 51 Baylor Scott & White Heart Hospital Plano
- 52 VA DOD Screening
- 53 VA Hospital Admin
- 54 Heart Rhythm Specialists
- 55 Houston Methodist
- 56 UT Health North Campus Tyler
- 57 UT Southwestern Medical Center
- 58 Whole Cardiac Wellness
- 59 ClearCardio

Idaho

- 28 Functional Medicine Institute - Idaho

Indiana

- 37 Indiana University - Executive Health
- 38 Indiana University Cardiovascular Genetics

Kentucky

- 35 Christ Hospital

Minnesota

- 29 M Health Heart Care

Michigan

- 30 Complete Family Care

Ohio

- 39 Cleveland Clinic Preventative Cardiology
- 40 South Dayton Metabolic Center

Tennessee

- 60 Chattanooga Heart Institute

Georgia

- 61 Emory Clinical Cardiovascular Institute
- 62 Emory Health - Cardiology/Executive Park
- 63 Emory Health Saint Joseph's

Florida

- 64 Ivy Cardiovascular and Vein Center

New York

- 41 Cornell Medicine Division of Cardiology
- 42 Columbia University Division of Cardiology

New Jersey

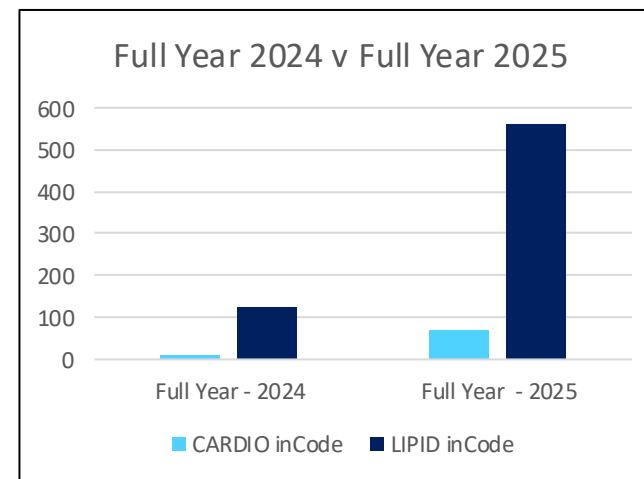
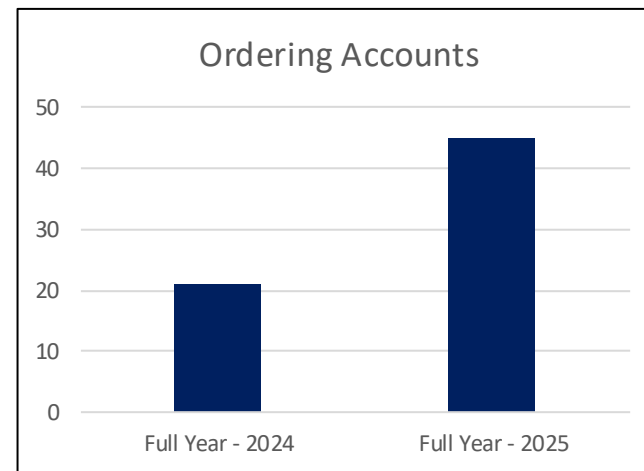
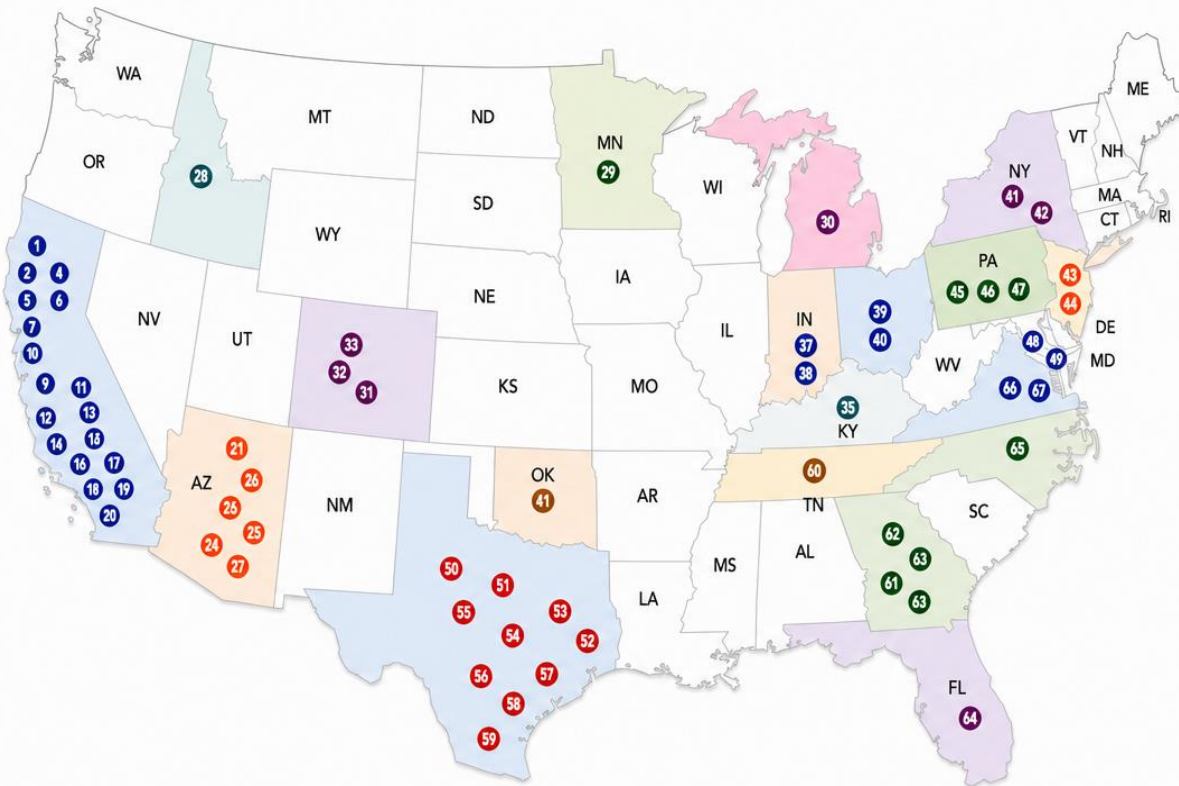
- 43 Advanced Heart & Vascular Institute
- 44 New Jersey Heart and Vein

Pennsylvania

- 45 Cardiology Consultants of Philadelphia
- 46 CCP - Roxborough
- 47 Penn Cardiology

Maryland

- 48 Baltimore Lipid Center
- 49 Johns Hopkins Hospital Center for Inherited Heart Disease



LIPID inCode

CARDIO inCode

	Total Addressable Market (TAM)	Serviceable Available Market (SAM)
LIPID inCode	\$ 1.8Bn	\$ 240m
CARDIO inCode	\$ 11Bn	\$ 4.5B

Pre Market Approval (PMA) submission

- **CARDIO inCode-Score:** Genetic risk assessment of coronary heart disease. Progressing Pre Market Approval for national distribution to US labs
- FDA 'Supervisory Review' completed April 2025 - Reduced outstanding deficiencies but upheld decision on further information to complete clinical validation.
- Recent FDA discussions have confirmed requirements to resolve deficiencies covering;
 - Population analysis, medical chart reviews
 - Analytical validation
 - Cybersecurity
- Targeted submission of *De Novo* PMA Q3.26

New York State Approval

- New York State DOH approval of CARDIO inCode-Score New York State clinical test permit for GENinCode Irvine, CA laboratory

- GENinCode and Thermo Fisher Scientific (TF) collaboration covering manufacturing, distribution and sales of CARDIO inCode-Score to laboratories in US and EMEA. CARDIO inCode-Score designed for use on Thermo Fisher QuantStudio (QS Dx) platforms*.
- TF is a major global provider of genetic reagents to labs with installed QuantStudio (QS Dx) platform user base.
- **Objective** - Prediction and prevention of Coronary Heart Disease, the leading cause of death globally and in US and UK. Advanced test content to be sold to labs.
- Non-Exclusive, 3 Year term (extendable). Territories: US and EMEA.
- Sales via TF lab network. End pricing TBA.
 - **Phase 1 - In House Assay:** Thermo Fisher provision of reagents for cardiovascular risk assessment on QS Dx platforms.
 - **Phase 2 - Medical Device:** Thermo Fisher to manufacture of CARDIO inCode-Score Medical Device once US-FDA/EU-IVDR approved on QS Dx platforms.
- **Licensing and commercial supply agreement** – Ongoing commercial discussions

* **QuantStudio platform** - Widely used globally in research, clinical diagnostic, and applied science fields for real-time PCR (qPCR) and digital PCR (dPCR) applications. The QuantStudio 5 Dx Real-Time PCR system is registered in more than 50 countries.

Commercial collaboration - Thermo Fisher Scientific workflow

Phase 1: 'In House Assay'

- TF introduces GENinCode to labs. TF mfg and sells reagents to labs to perform cardiovascular risk testing.
- GENinCode sells the license to SITAB system and reporting i.e. SITAB's cloud-based analysis and AI bioinformatics
- Lab charge to patient/payor ~\$500/test for Medicare (Self-Pay and healthcare provider costs to be determined)

Phase 2: 'Medical Device'

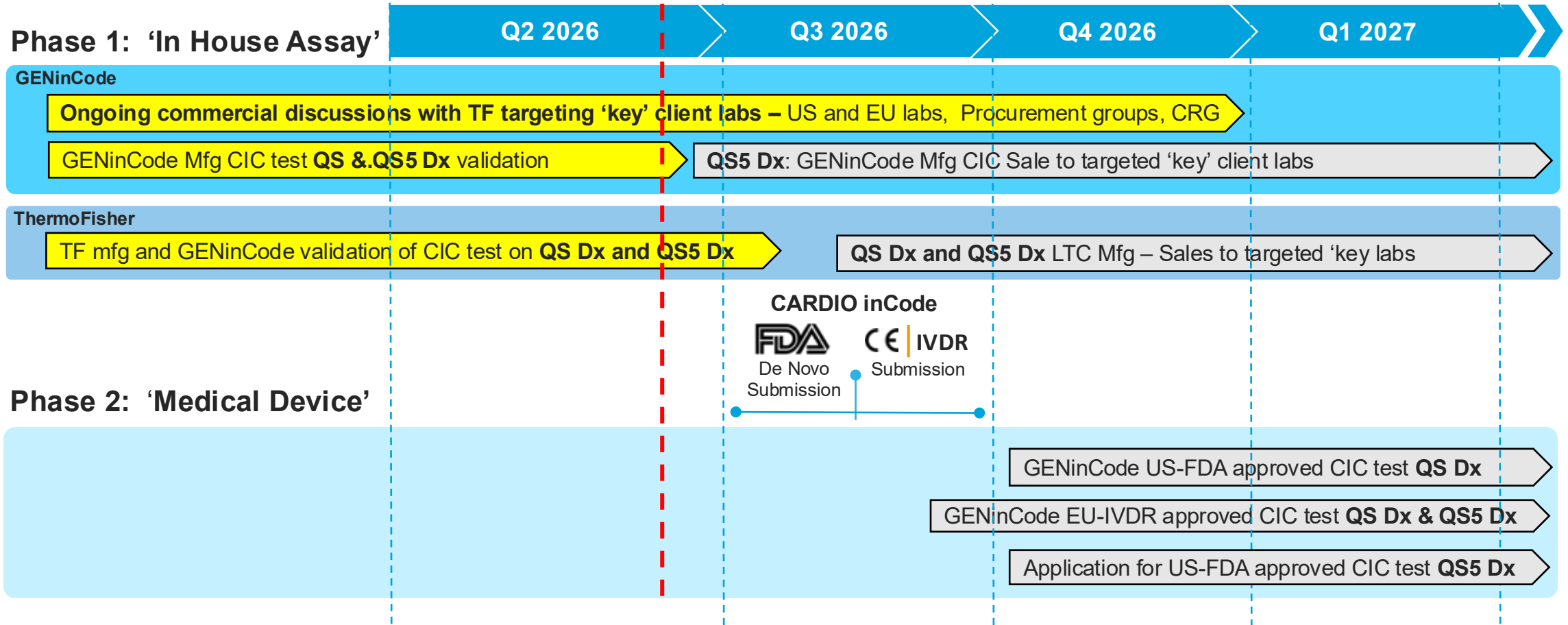
- TF introduces GENinCode to labs. TF mfg CARDIO inCode-Score as a **Medical Device** for labs to perform CARDIO inCode-Score (PRS).
- GENinCode sells CARDIO inCode-Score full test system including reporting i.e. SITAB's cloud-based analysis AI bioinformatics
- Lab charge to patient/payor ~\$500/test for Medicare (Self-Pay and healthcare provider costs to be determined)

Indicative Figures US\$	Current Full Service	Thermo Fisher (IHA/Med Device Lab Distribution)
Selling Price	\$300-\$500 #	\$125-\$250
COGS	\$25-\$35	\$25
GM%	90%+	80%+
Laboratory, SITAB and Selling Overheads	All overheads	No lab cost, SITAB software, shared selling

x Lab multiplier
x Minimum test pack size
x International reach

Medicare reimbursement - ~\$500/test

GENinCode and TF - CARDIO inCode-Score (CIC) Indicative timelines



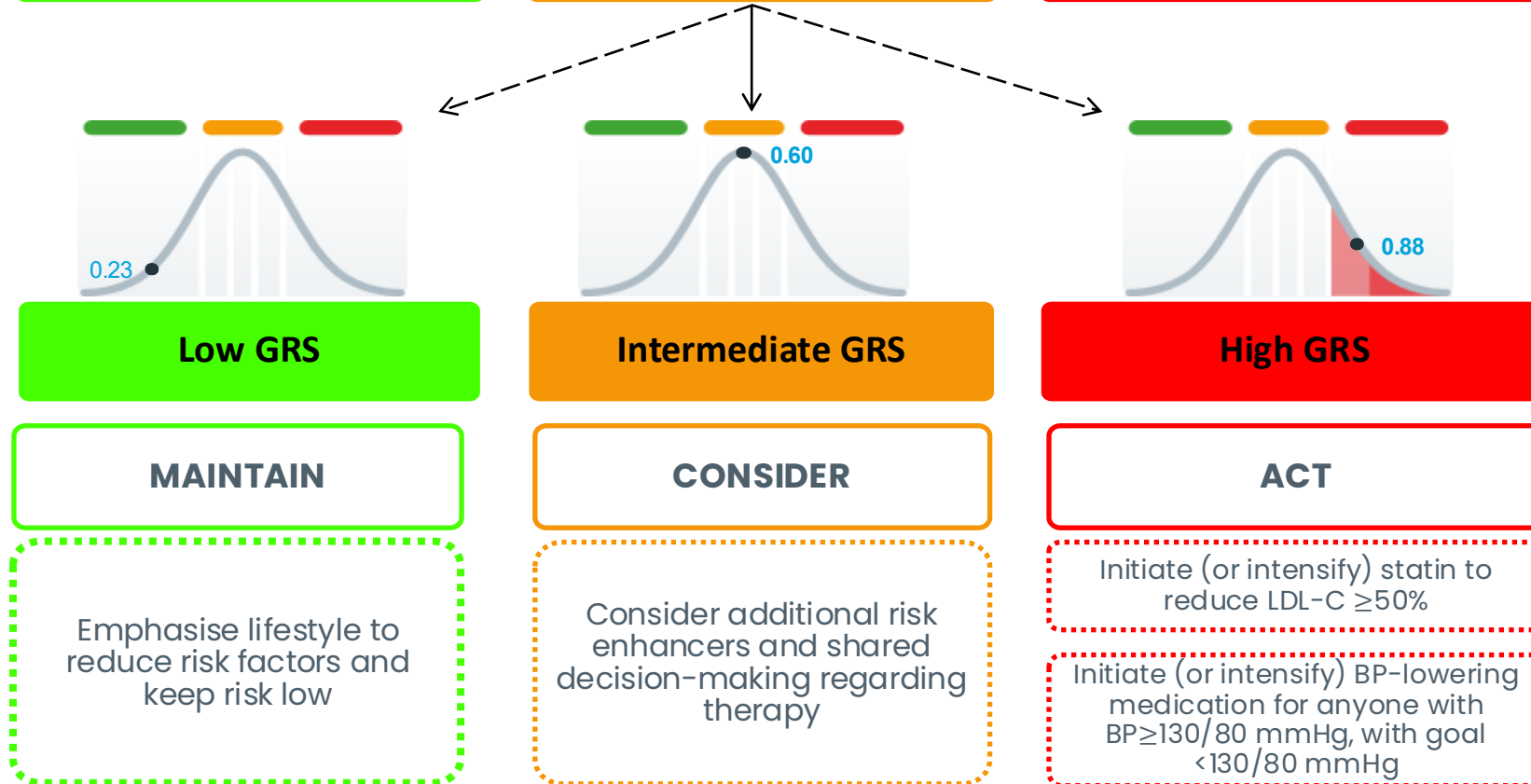
- Collaboration accelerates existing CARDIO inCode-Score sales program
- New growth via US labs (incremental to physician/clinic/hospitals) and avoids high investment in sales resource
- Increased competitive advantage – leading test, clinical evidence, low cost and scalable via Thermo Fisher
- Strategy and relationship expandable to other GENinCode commercial test products based on success of CARDIO inCode-Score

CARDIO inCode - Polygenic Risk Score: Clinical utility

Primary Prevention:

Age 40–75 y, LDL-C ≥ 70 – <190 mg/dL, without diabetes mellitus, begin risk discussion with 10-year ASCVD risk

Risk of disease based on clinical risk factors



Risk reclassification and stratification based on genetic risk score (GRS)

LIPID inCode: US Launch and Education

Familial Hypercholesterolemia (FH) is a global autosomal (inherited) genetic disorder of lipid metabolism causing raised blood cholesterol, the early onset of cardiovascular disease and premature mortality (mainly from heart attacks). FH responds well to drug treatment so early diagnosis is vital.

FH testing represents a **\$1.8Bn** market opportunity in the US



Value Proposition

Monogenic + Polygenic Test

- **FH testing 'Tier 1' genomic test** by Centers for Disease Control and Prevention (CDC)
- **LIPID inCode provides commercially available Monogenic + Polygenic test**
- **Scientific expert panels support the inclusion of polygenic risk** for patients that are negative for monogenic FH



HCP Adoption

Engagement with Key Influencers

- **Targeted engagement plan focused** on engaging top **250 physicians** in lipidology and preventative cardiology
- Supporting key programs and conferences with **FH foundation, National Lipid Association (NLA)**, and the **American Society of Preventative Cardiology (ASPC)**



Access and Distribution

Favourable Reimbursement Environment

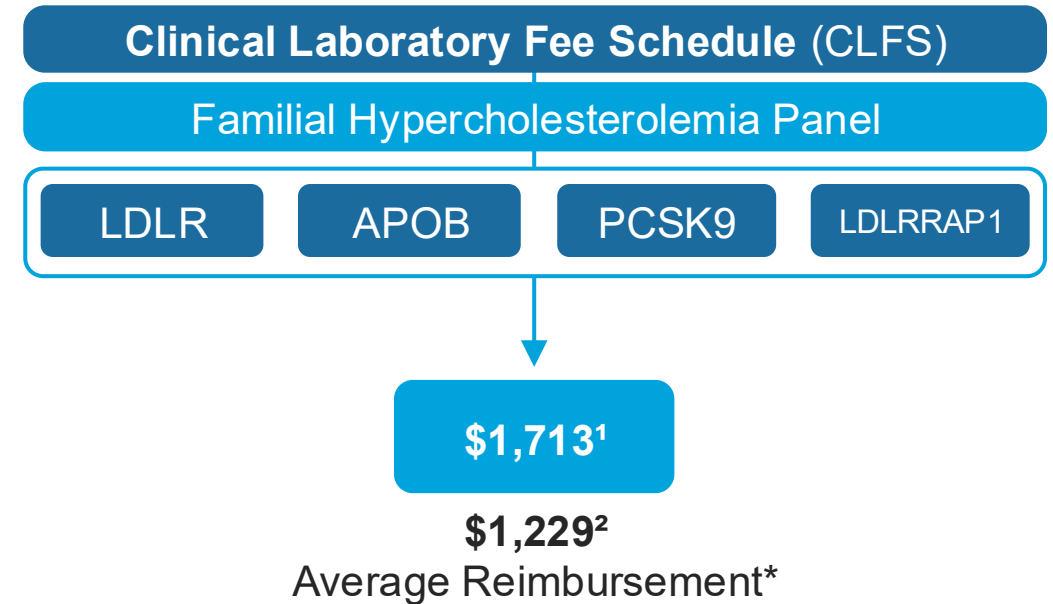
- **Established ICD-10 and CPT Codes for FH Testing** should enable rapid adoption of testing with targeted payers
- **Favourable reimbursement policies** in place for FH testing with **IDNs, regional, and national payers**

LIPID inCode: US Market Assessment

The US target market for **LIPID inCode** includes **1.5M** patients with diagnosed FH and undiagnosed probable FH

Physicians see **LIPID inCode** as a targeted test for patients with suspected, probable, or confirmed familial hypercholesterolemia

Target Patients for LIPID inCode	Patients in Target Segment
<p>Clinically diagnosed FH: Estimated 200K Patients</p> <p>ICD-10 code for Familial Hypercholesterolemia (FH) These patients have not been tested for FH genetic variants</p>	0.2M ¹
<p>Undiagnosed Probable FH</p> <p>Predictive modeling based on clinical features in US population</p>	1.3M ²
Total	1.5M



1. Eversana RWD, Familial hypercholesterolemia patient cohort. Sept 2022 (SAM) + FH Foundation
 2. Kullo et al, Familial Hypercholesterolemia: A reportable disorder. Circulation 2020

Genomic testing for cardiovascular conditions

- ✓ Analogue to digital
- ✓ Treatment to prevention

Summary of innovation

A partnership between the technology company GENinCode PLC and the North East Genomic Laboratory Hub (GLH) has successfully identified people with familial hypercholesterolaemia (FH), a monogenic condition that can lead to premature coronary heart disease. The LIPIDinCode test for FH includes Lipoprotein(a), polygenic LDL and CAD risk assessment for cardiovascular disease (CVD) prevention.

Familial hypercholesterolaemia is a genetic condition that affects 1 in 250 people and reduces the liver's ability to process cholesterol and increasing the risk of developing heart or circulatory disease.

FH remains underdiagnosed, with only 5.8% identified against a 25% NHS Long Term Plan target set in 2019.

Diagnosis of FH relies on LDL/total cholesterol levels, family history of premature coronary disease, and physical examination, but genetic testing is essential for confirmation.

Referral to specialist lipid clinics is often needed, but waiting times can exceed 52 weeks. Additionally, limited capacity in some Genomic Laboratory Hubs (GLHs) has delayed genetic testing and treatment initiation. GENinCode has successfully shortened this pathway.

Network support

Health Innovation North East and North Cumbria (NENC) with Health Innovation North West Coast are working with NHS England's CVD Prevention Team and NHS Genomics Service to explore ways in which innovations such as GENinCode can be implemented into CVD diagnostic pathways.

Scalability prospect / next steps

Faster genetic testing, at reduced cost could contribute to the shift to disease prevention.

Understanding monogenic (FH) and polygenic risk of CVD, and incorporating Lipoprotein(a), aligns to regional and local CVD prevention strategies.



2,550
FH samples tested

Impact of innovation

- ✓ **2,550** FH samples tested
- ✓ **53** NENC referring clinicians supported
- ✓ **490** positive FH patients diagnosed and **19.2%** of patients with genetically confirmed FH
- ✓ GENinCode genetic testing average turnaround time of **10-15 days** compared to previous 3-4 months.

Health and care system success

- Improved capacity in lipid clinics through reducing waiting lists.
- Improved turnaround times for genetic tests, with greater patient and clinician satisfaction.
- Created capacity within GLHs, releasing up to 3-4 days per week for clinical scientists.

Economic success

The cost of GENinCode testing is half the NHS cost. It provides a more comprehensive CVD prevention assessment, leading to significant cost-savings. NENC is pioneering prevention of CVD using polygenic risk assessment to improve patient outcomes.



“ We are delighted to support the NHS North of England through our collaboration with Health Innovation North East and North Cumbria by reducing the cost of genetic testing and improving turnaround times to identify individuals at high risk of CVD. ”

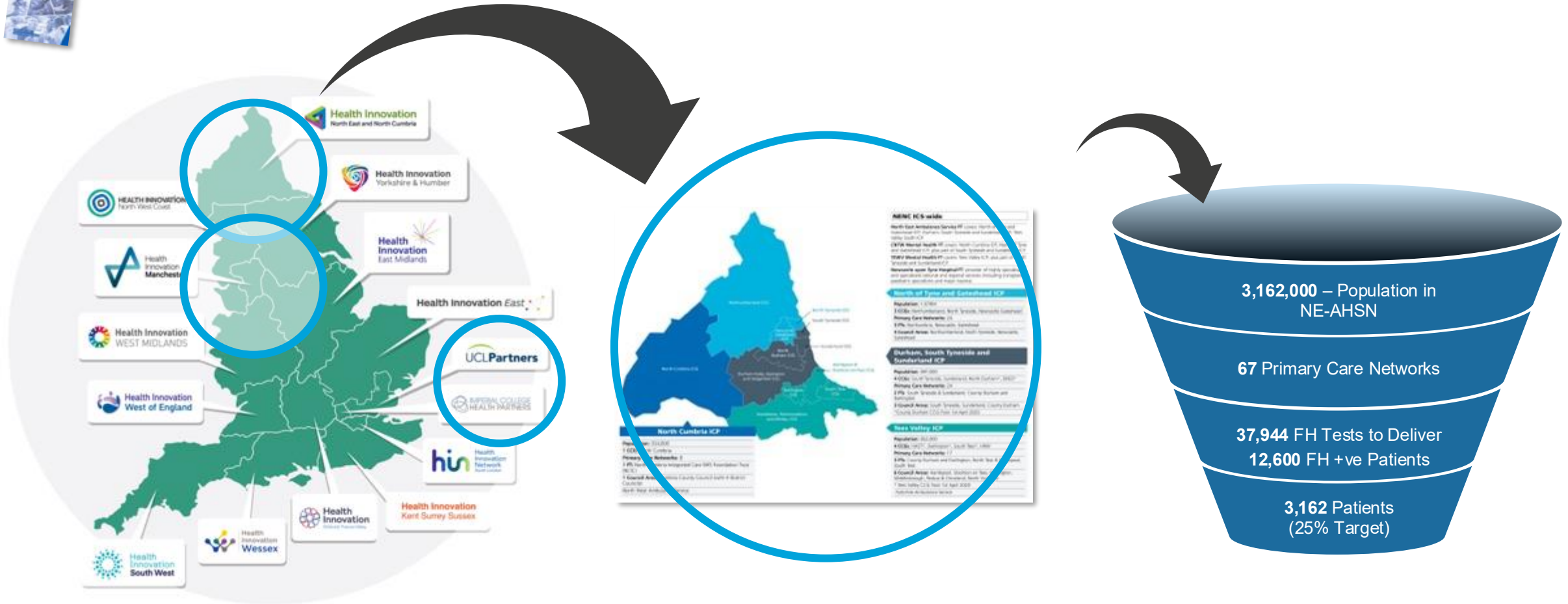
Matthew Walls
CEO, GENinCode PLC

https://thehealthinnovationnetwork.co.uk/case_studies/genomic-testing-for-cardiovascular-conditions/

NHS: HIN's – Expansion to Prevention of CVD



NHS Long-Term Plan to improve FH diagnosis rates to at least **25%** of FH patients



- Phased implementation of LIPID inCode to achieve NHS targets
- Pharma collaborative discussions targeting patients 'most in need' of lipid lowering medications to prevent heart disease

EU Strategy

- Revenue growth driven by CARDIO inCode regional pilots and LIPID inCode supported by Spanish regions 'FH' detection plans
- Regional roll-out of CARDIO inCode for Cardiovascular Prevention in Primary Care
 - Extremadura region - CARDIO inCode pilot in Primary Care
 - Catalonia region - CARDIO inCode pilot in Primary Care
 - Negotiations ongoing for pilots in further Spanish regions: Baleares, Castilla y León, Asturias, Basque Country and Andalucia
- Growth via Public Hospital implementations
 - LIPID inCode, THROMBO inCode and CARDIO inCode services and kit implementations
- Growth via strategic alliance for CARDIO inCode, THROMBO inCode and LIPID inCode
 - **Synlab (now Eurofins) – Spain:** Collaboration in IVF Clinics
 - **Sohin Genetics – Mexico:** Distribution in Mexico
- Expanding direct business operations in Italy
 - Extending collaborations with Fondazione SISA (LIPID inCode)
 - Direct commercial promotion with CARDIO inCode, THROMBO inCode, LIPID inCode and SUDD inCode
- Strengthening LIPID inCode sales in Germany with Uniklinikum

Thermo Fisher CARDIO inCode-Score collaboration to support lab revenue growth across EU

2025 Final Results

Revenues £3.1M, 14% year-on-year growth across EU and US

Gross Profit margin increased to 59% (2024: 53%) reflecting improving geographic margin mix from UK, EU and US.

Adjusted EBITDA loss £4.9M (2024: £4.4M). Excludes non-cash movements of share-based costs (£0.8m).

Comprehensive loss of £5.5M reflecting growth in revenues, margin, increased commercial support and reduced R&D tax credit.

Cash balances - £0.8M at end Dec 2025 (2024: End Dec £1.1M). Net fundraising proceeds of £4.3M completed in March 2026.

Revenues	2025	£3.1M
	2024	£2.7M

Gross Profit	2025	£1.8M (59%)
	2024	£1.4M (53%)

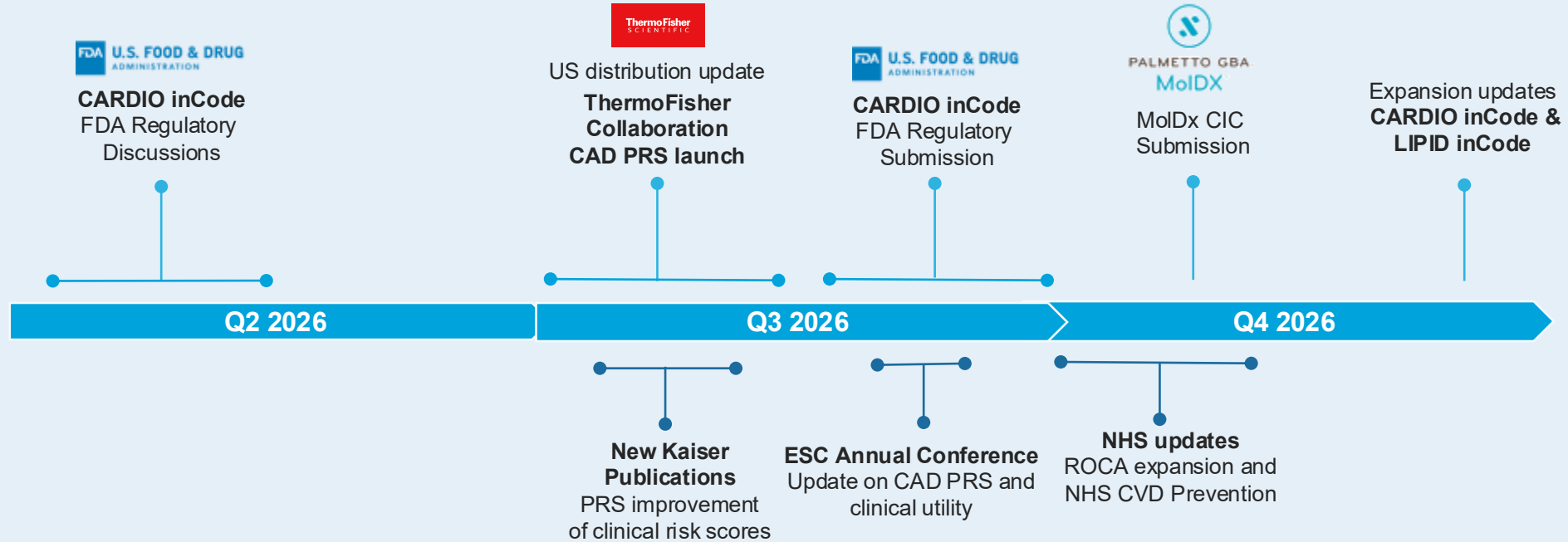
Adjusted EBITDA loss	2025	(£4.9M)
	2024	(£4.4M)

Comprehensive Loss	2025	(£5.5M)
	2024	(£4.3M)

Cash Reserves	2025	£0.8M
	2024 (Dec)	£1.1M

2026 Key events and expected newsflow

Indicative timeline

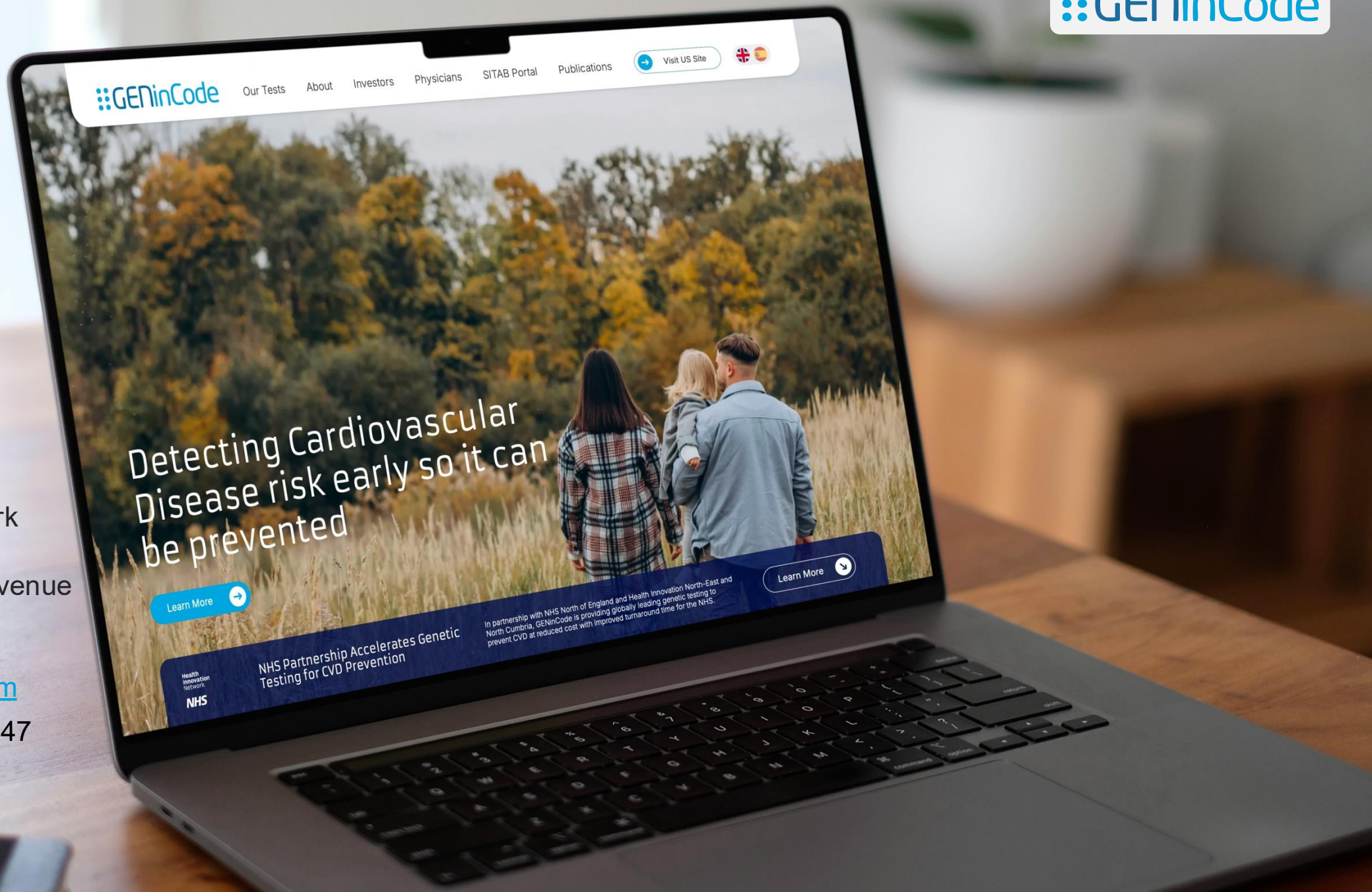


- Thermo Fisher commercial updates Q3.26
- FDA PMA filing Q3.26 and anticipated approval end Q4.26
- NHS updates CVD prevention and ROCA
- 2026 ESC Annual Conference, Munich – Clinical update on CAD PRS

Summary and outlook

- **Revenue** increased 14% YOY to £3.1m with continued cost containment.
- **Preparations to file CARDIO inCode-Score FDA De Novo PMA submission** to accelerate US sales.
- **Commercial expansion of LIPID inCode and CARDIO inCode** across the US, EU and UK markets strengthened by collaboration with Thermo Fisher.
- **Thermo Fisher commercial discussions ongoing** for CARDIO inCode-Score test distribution.
- **Ongoing strategic discussions with NHS** for prevention of heart disease.
- **Expansion of CARDIO inCode pilots in Catalonia, Extremadura and introduction to other Spanish regions.**
- **Expansion of the MVZ Uniklinikum, Germany collaborative programme.**
- **Expanding ROCA commercial program** with the NHS and European clinics.
- **Breakeven over the medium term.**





Detecting Cardiovascular Disease risk early so it can be prevented

[Learn More](#)

[Learn More](#)



NHS Partnership Accelerates Genetic Testing for CVD Prevention

In partnership with NHS North of England and Health Innovation North-East and North Cumbria, GENinCode is providing globally leading genetic testing to prevent CVD at reduced cost with improved turnaround time for the NHS.

GENinCode PLC
Oxford Science Park
John Eccles House
Robert Robinson Avenue
Oxford UK

www.genincode.com

Tel: +44 1865 955847

LIPID inCode: Family Heart Foundation - DISCOVER FH program

- Collaboration with FH Foundation to use LIPID inCode for testing in US Primary Care settings for the diagnosis of familial hypercholesterolemia (“FH”)
- First phase funded by a grant from the US DOD, the DISCOVER FH collaboration relates to “Research to improve early diagnosis of familial hypercholesterolemia (FH) and the implementation of diagnostic tools, including paediatric population.”
- LIPID inCode also provides physicians with polygenic hypercholesterolemia (high levels of cholesterol) and coronary heart disease risk (CARDIO inCode).
- DISCOVER FH collaborators include: **UT Southwestern Medical Center, University of Pennsylvania, Geisinger, West Virginia University, Mayo Clinic and Veterans Association**
- Less than 30% of people with FH in the US have been identified, despite the efforts of the Centers for Disease Control and Prevention (CDC) to prioritize FH for early detection, cascade screening and proactive treatment with cholesterol-lowering drugs



- Risk of Ovarian Cancer Algorithm (ROCA) test. NHS risk assessment for early detection of ovarian cancer
- NICE Guidance (March 2024)¹ : Ovarian Cancer; Identifying and managing familial and genetic risk
- Key parts to guidance 1.) Identifying high risk individuals 2.) Genetic testing 3.) Support individuals with a positive result;
 - **Preventative surgery**
 - **Surveillance using the ROCA Test**

NHS commissioning

- Collaboration UCLH NHS Foundation Trust (UCLH) and the North Central London (NCL) Cancer Alliance - Sept 2025
- YTD Dec 2025: 652 tests sold; £70,315 revenue (Dec 2024: 64 tests; £7,952). Jan - May 2026: 227 tests sold
- Second London Region anticipated Sept 2026; Cancer Alliance ‘kick-start’ funding. Multiple other regions seeking adoption
- Process automation on NHS side underway, facilitated by migration to SITAB
- Recurring revenue: 1 patient; 15 tests over 5 years = £1,500; 10 years = £3,000

Europe

- Switzerland and Austria growing awareness due to clinician education programs
- Private pay limiting adoption
- Adoption in Spain expected to start 2H 2026.

NHS TAM: based on prevalence of BRCA mutations in female population of England and Wales which = 0.46%
18M women in England and Wales over 35y
Number eligible for ROCA test = 82,800
Evidence shows 40% of women choose to defer preventive surgery = 33,120
33,120 X £300/Yr = £9.94m

1. NICE Guidance: [Overview](#) | [Ovarian cancer: identifying and managing familial and genetic risk](#) | [Guidance](#) | NICE

UK Strategy: Cardiovascular Disease Prevention

Management of cholesterol and CVD genetic risk

Familial Hypercholesterolemia (FH) is a global autosomal (inherited) genetic disorder of lipid metabolism causing raised blood cholesterol, the early onset of cardiovascular disease and premature mortality (mainly from heart attacks). FH responds well to drug treatment so early diagnosis is vital.

- Collaboration with NHS for GENinCode to deliver FH to support '2019 NHS Long Term Plan' to increase the detection of people with FH
- **Completed and published** successful NHS FH comparative study in December 2021
- **Successfully completed FH test pilot with NE-AHSN 2022** (Centre of Excellence for familial hypercholesterolemia & NHS FH strategy)
- **2023 - Agreed NHS implementation plan** and initial funding with NE-AHSN for introduction of LIPID inCode
- NHS Cardiovascular Disease Prevention Program - **September 2025**
Delivered >2,800 tests in North of England



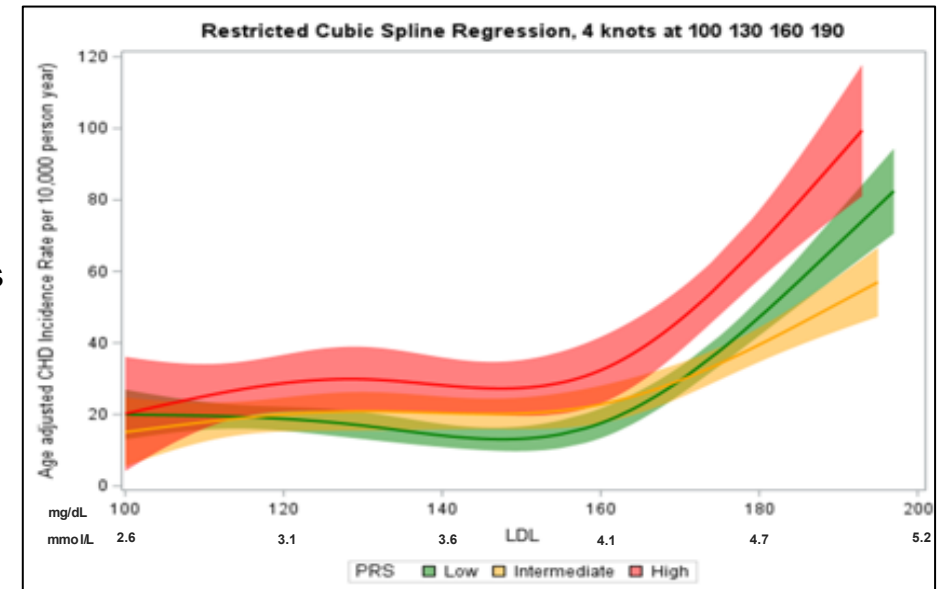
Case Study

- FH estimated to affect 1 in 250 of the UK population i.e., between 230k-260k people
- Roughly 6-10% of this population have been genetically diagnosed in England
- UK NHS target is to detect 25% of FH population

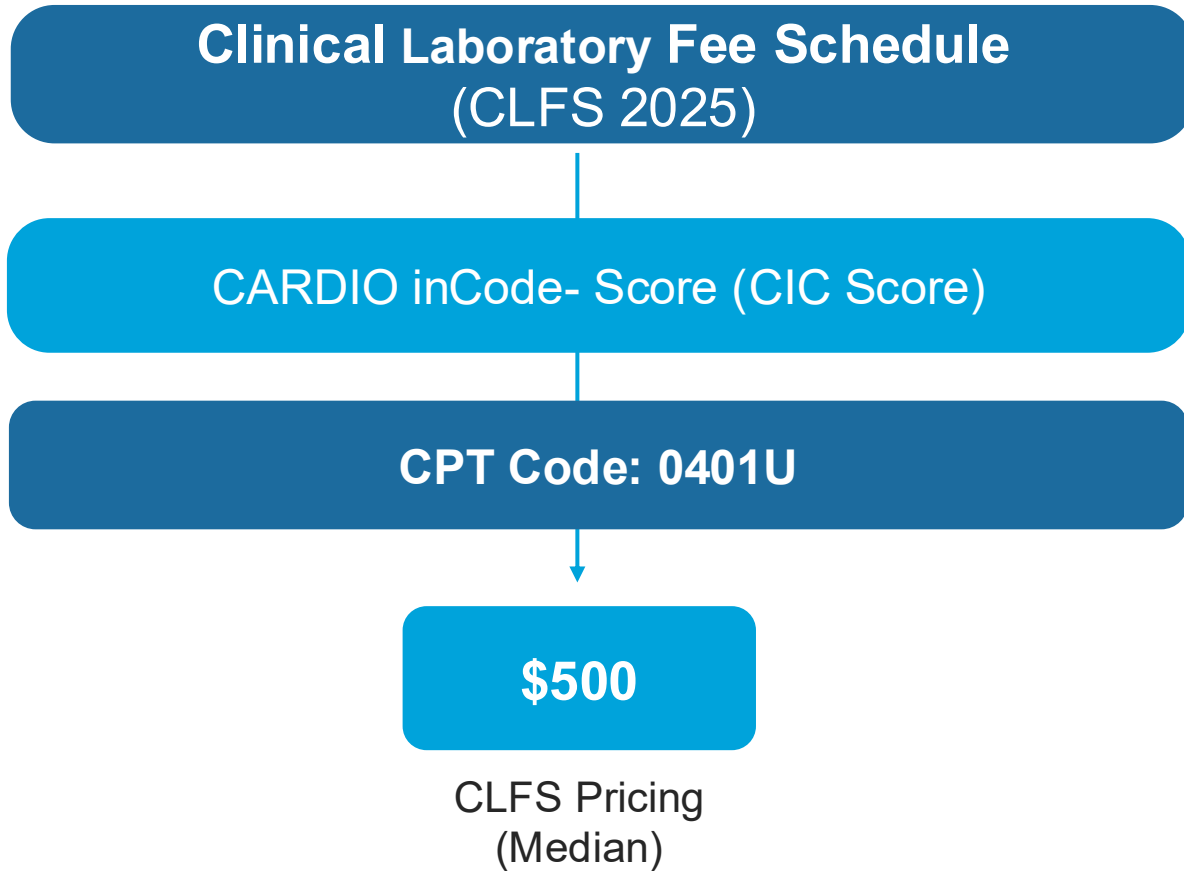


US Strategy: Polygenic risk modulates cholesterol risk **CARDIO** inCode-Score

- Polygenic risk score provides identification of a patient's genetic 'lifetime risk of CHD' **earlier**, prior to onset of clinical risk factors
- Identifies **'high risk'** genetic patients **undetected** by 'traditional' clinical risk assessment – Differentiating patients that need treatment most
- Enables **up-classification** of clinical risk based on a patient's polygenic risk score
- CHD polygenic burden is **actionable** and can be partially attenuated by treatment, enabling more effective and timely prevention plans, including lipid lowering/statin treatment
- Is an **independent** risk factor (alongside clinical risk) and key to accurately determining overall CHD patient risk
- Educates young and older patients on genetics and lifestyle. Empowers patients (and physicians) to reduce risk of disease through knowledge and improved risk assessment



CARDIO inCode: Reimbursement Rates - CMS



Key Coding/Reimbursement Activities

- CARDIO inCode-Score **CPT PLA coding (0401U) approved** by the **American Medical Association**
- Discussions ongoing with **CMS** (Centers for Medicare and Medicaid Services and MoIDx) for final coverage pricing
- **Clinical validation studies published** to support payer tech assessments and improve dossiers
- Private payer engagements ongoing

CARDIO inCode: US Market Assessment

Initial CARDIO inCode Target Market: **22M**
Receptive Physicians **~8.5M**, if covered by insurance

About half of physicians³ would order **CARDIO inCode**, if covered by insurance, for two types of patients: intermediate risk who are not compliant or controlled, and low risk patients with family history. Prior authorisation, expected by payers, reduces the number of physicians who would order. Assumes physicians expect to order the test once per patient, i.e., no recalculation of risk scores.

(Approx 82M Americans living with CVD)

Target Patients for Cardio inCode <i>(based on physicians interviewed)</i>	Patients in Target Segment	No. Likely to get Prescription
Intermediate Risk¹ Patients inadequately controlling risk e.g., not taking statins or making lifestyle changes (estimated 33% of intermediate-risk patients) ³	9M	4.4M
Low Risk¹ Patients with family history (estimated 13% of low-risk patients) ²	13M	4.1M
Total	22M	8.5M

1. Goff, David C Jr et al. "2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." Circulation. 2014

2. Moonesinghe, Ramal et al. "Prevalence and Cardiovascular Health Impact of Family History of Premature Heart Disease in the United States/ 2007-2014." JAHA. 2019

3. EVERSANA interviews with 45 potential prescribers of CiC. January 2021. Sample size may not be representative of market opportunity

CARDIO inCode: Recent Clinical Publications

1. Clinical utility of CARDIO inCode – Score, polygenic risk score (PRS) for incident CHD: interplay with lifestyle in a multi-ethnic cohort of more than 60,000 individuals: Iribarren et al., International Journal of Cardiology Cardiovascular Risk and Prevention 2024;23:200350

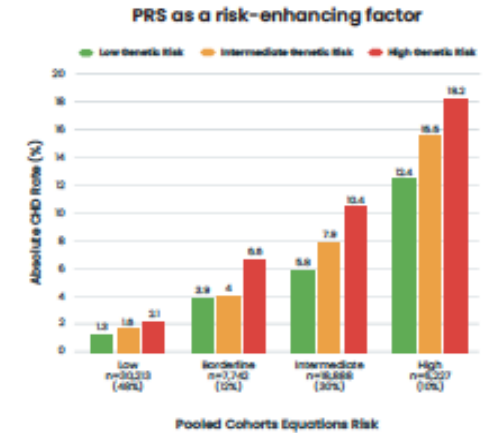
- Individuals with a high PRS can reduce their incidence of CHD by 52% by changing their lifestyle
- By focusing treatment on those individuals with a high PRS we can halve the numbers needed to treat (NNT) to avoid an event.

Age adjusted CHD rates per 10,000 Person-years by Individual and Combined Lifestyle Factors and Polygenic Risk



2. Polygenic risk and incident coronary heart disease in a large multiethnic cohort: Iribarren et al., American Journal of Preventive Cardiology 2024;18:100661

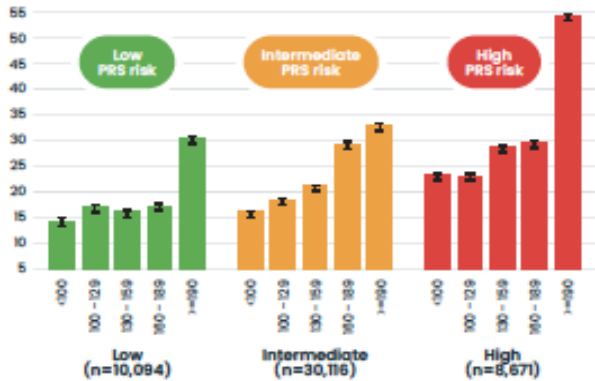
- CARDIO inCode-Score PRS is independently associated with an increased (lifetime) risk of incident CHD
- PRS and incident CHD was consistent in PRS scoring across sexes and multiethnic groups
- Provided additional risk stratification within categories of the Pooled Cohorts Equations (PCE) risk, particularly in individuals with borderline and intermediate PCE risk
- By incorporating the CARDIO inCode-Score® PRS into risk assessment identifies individuals at higher risk who would benefit from statin therapy or intensified treatment
- In combination with traditional clinical risk factors improves the accuracy of risk prediction for CAD.



3. Joint consideration of LDL-C and polygenic risk for incident coronary heart disease in a multi-ethnic cohort of 48,881: ESC Preventive Cardiology, Athens, April 2024

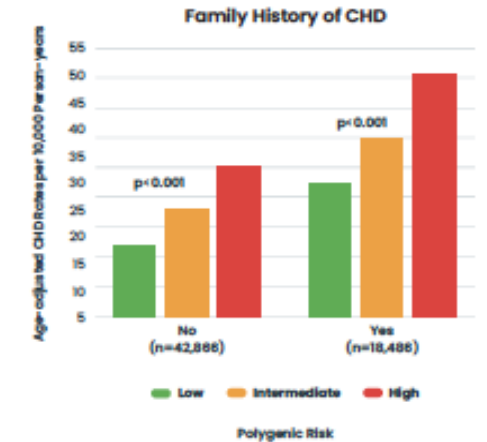
- Chart shows that subjects with high polygenic risk should not have LDL-C levels above 130 mg/dL as their CHD risk is similar to those with LDL-C levels \geq 190 mg/dL and a low polygenic risk
- PRS provides additional risk factor and risk stratification and importance, especially for those with LDL-C between 130 and 189 mg/dL.

Age-adjusted CHD rates per 10,000 person-years Across LDL-C levels and polygenic risk



4. Interplay between Family History and Polygenic Risk for Coronary Heart Disease: A Cohort Study among over 60 thousand Individuals: ESC Annual Congress, London, 2nd September 2024

- PRS and family history CHD are positively correlated, and both independently contribute to risk of incident CHD
- 42% higher risk if +family history CHD
64% higher risk if high polygenic risk
- PRS predicts similar increased CHD risk in persons with and without family history CHD
- The joint effect of +family history CHD and high PRS: 2.3 increased hazard
- Relying solely on self-reported family history is insufficient to fully characterise the genetic contribution to CHD and PRS is recommended.



Appendices: Final Results 2025 - P&L

	2025	2024	+/-
	£'000	£'000	£'000
Revenue	3,076	2,701	375
Cost of sales	(1,272)	(1,275)	3
Gross profit	1,804	1,426	378
GM %	59%	53%	6%
Administrative expenses	(6,670)	(5,873)	(797)
AEBITDA	(4,866)	(4,447)	(419)
Depreciation/Amortisation	(266)	(347)	81
Share based payments	(761)	(397)	(364)
Impairment Loss	-	(149)	149
Reversal of contingent consideration provision	-	206	(206)
Operating Loss	(5,893)	(5,134)	(759)
Other Income	43	99	(56)
Finance Charge	(13)	(48)	35
Loss Before Income Tax	(5,863)	(5,083)	(780)
Income Tax	158	649	(491)
Loss for the Year	(5,705)	(4,434)	(1,271)
Exchange diff on translation of foreign ops	198	132	66
Total comprehensive loss for the Year	(5,507)	(4,302)	(1,205)

Appendices: Final Results 2025 Balance Sheet

	2025 £'000	2024 £'000	+/- £'000
ASSETS			
Non-current assets			
Intangible assets	98	138	(20)
Property, Plant & Equipment	113	425	(121)
Right of use asset	124	282	(83)
Goodwill	-	149	-
Total non-current assets	335	994	(224)
Current assets			
Inventory	73	84	(53)
Trade and other receivables	1,074	582	261
Cash and cash equivalents	827	2,484	(283)
Financial assets	68	42	13
Total current assets	2,042	3,192	(62)
Total assets	2,377	4,186	(286)
Equity			
Shareholders' Equity			
Share capital	2,869	958	1,099
Share premium	21,126	15,551	2,644
Other reserves	1,779	291	959
Retained earnings	(25,650)	(15,551)	(5,705)
Total equity	124	1,289	(1,003)
LIABILITIES			
Non-current liabilities			
Contingent consideration	-	-	-
Lease liability	51	147	(96)
Deferred tax	2	12	(10)
Current liabilities			
Trade and other payables	2,105	1,290	815
Lease liability	95	87	8
Total liabilities	2,253	1,536	717
Total equity and liabilities	2,377	2,663	(286)

Appendices: Final Results Cash Flow Statement

	2025	2024	+/-
	£'000	£'000	£'000
Loss before taxation	(5,863)	(5,083)	(780)
Adjustments	997	636	361
Operating Loss before working capital changes	(4,866)	(4,447)	(419)
Working capital changes	742	(726)	1,468
Net cash outflow from operating activities	(4,124)	(5,173)	1,049
Investing activities	(1)	50	(51)
Financing activities	3,642	3,645	(3)
Net increase in cash and cash equivalents	(483)	(1,478)	995
Cash and cash equivalents at beginning of year	1,110	2,484	(1,374)
Movement in retranslation	200	104	96
Cash and cash equivalents at end of year	827	1,110	(283)