::GENinCode

Prevention of Cardiovascular Disease (CVD)

Detecting CVD risk early so it can be prevented **Interim Results 2025** September 2025

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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.

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, IT systems and development.

Globally leading 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.

















Atrium Health











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



2025 Interim Report Summary



Operational Highlights

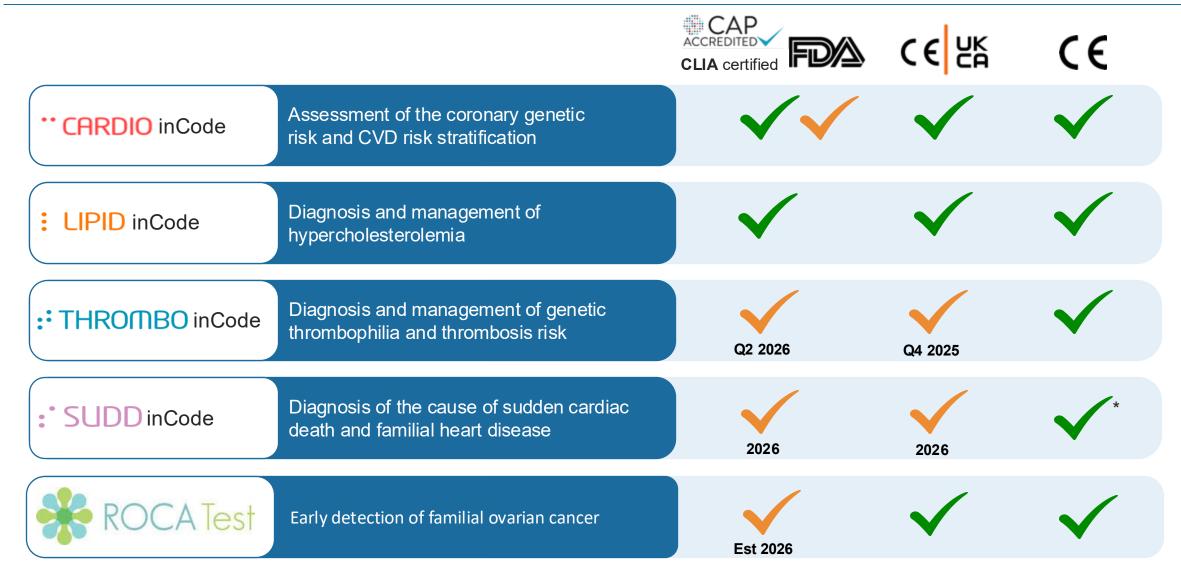
- Announcement of first ROCA commercial contract with NHS University College London Hospitals NHS Foundation Trust ('UCLH') and the North Central London ('NCL') Cancer Alliance for surveillance of women at high genetic risk of ovarian cancer
- Increasing US commercial sales of LIPID inCode® and CARDIO inCode-Score®. Over 40 US clinics and institutions now onboarded for risk assessment and preventive testing of coronary heart disease
- Whilst disappointing not to have received approval during the period, CARDIO inCode-Score FDA 'De Novo' Supervisory Review was completed with agreement of outstanding deficiencies and process to submit additional information.
- Ongoing discussions with US commercial partners for CARDIO inCode-Score test distribution
- Inclusion of CARDIO inCode-Score® in 2025 US clinical lab fee schedule
- NHS expansion of LIPID inCode® for FH diagnosis in North of England however, progress has been slower than expected due to the major strategic, organisational and funding changes across the NHS.
- Growth of LIPID inCode® in University Clinic Dresden, Germany for primary care diagnosis of Familial Hypercholesterolemia
- Growth of LIPID inCode® and THROMBO inCode® in Spain and Italy. CARDIO inCode-Score® pilot progressing in Extremadura and Catalonia regions of Spain
- Presentations at American Society of Preventive Cardiology Annual Meeting and European Society of Cardiology World Congress on genetic modulation of cholesterol risk

Financial highlights

- First half revenues increased 15% to £1.60m (30 June 2024: £1.39m), driven by growth in UK, EU and US
- Successful completion in March of £3.7m (Gross £4.1m) fundraising to support scale up and expansion
- Adjusted EBITDA loss, excluding unrealised forex loss, of £2.07m (30 June 2024: loss of £2.05m)
- Cash reserves of £2.44m at 30 June 2025 (31 Dec 2024: £1.11m)



Product Portfolio: Cardiovascular Disease (CVD)



^{*}Sudd inCode EU clinical lab services under ISO15189



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













Product Referral from HCP / Clinic and Sample Collection Sample Collection and DNA Isolation Genotyping and Sequencing Bioinformatics and Al

Clinical Report Generation Treatment Pathway

SITAB Bioinformatics and Online Reporting Tool

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









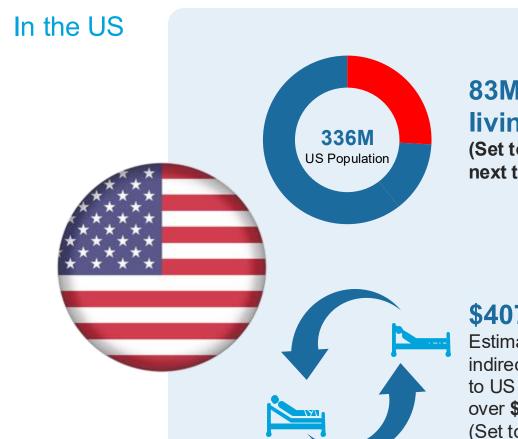








Cardiovascular Disease is the Leading Cause of Death Worldwide¹



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

2030 2015 \$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.00000000000001258

^{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



- 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 \$500 test*
- MolDx submission for US state-based reimbursement in preparation post FDA approval



Commercial:

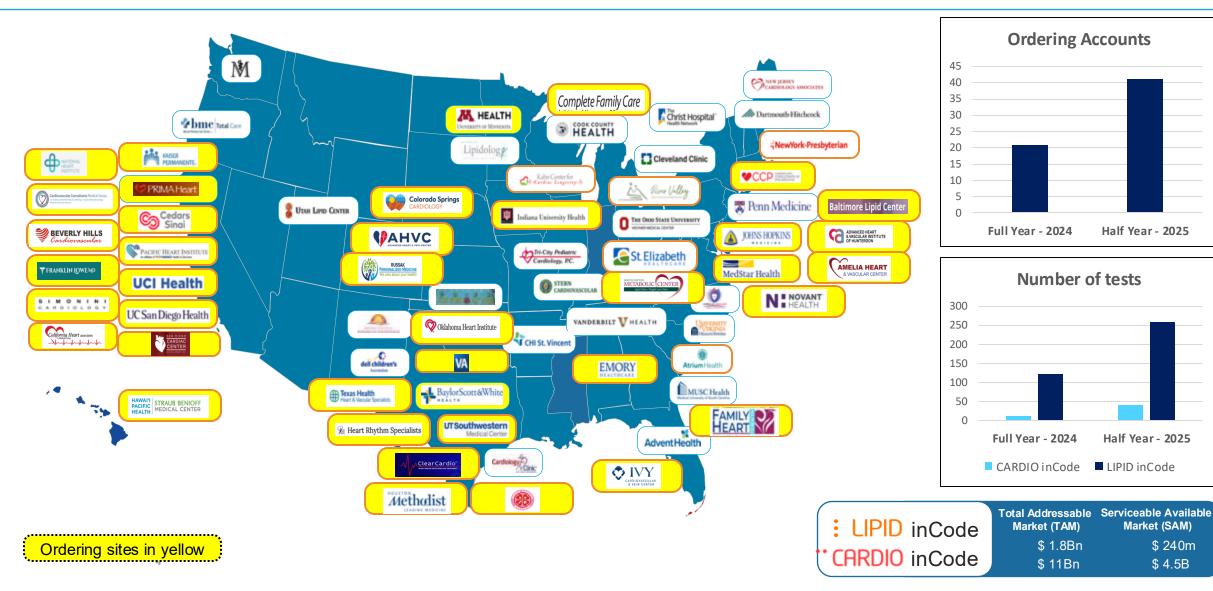
- KOL focus, education and SITAB portal onboarding
- Commercial Payer Discussions progressing benefits investigation and 'out of network' payer coverage
- Service based testing across institutions, community clinics and executive health

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





US Program Sites: 40 active ordering sites





Market (SAM)

\$ 240m

\$ 4.5B



- De Novo Supervisory Review and remaining deficiencies

- **CARDIO inCode-Score**: Genetic risk assessment of coronary heart disease. Progressing FDA Medical Device regulatory 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;
 - Population analysis, medical chart reviews
 - Analytical validation
 - Cybersecurity
- Targeted submission of *De Novo* information Q1.26
- Commercial distribution discussions ongoing with US national providers

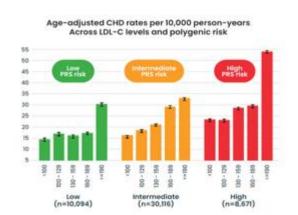


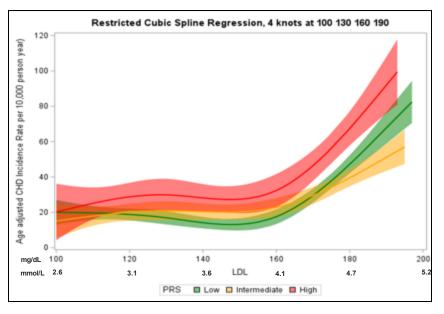
US Strategy: Polygenic risk modulates cholesterol risk

- Polygenic risk score provides identification of a patients 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-Score

- 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 =>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.







CARDIO inCode: AHA, JACC and ESC statements - Polygenic Risk Scores

Circulation

Volume 75 No.22, June 2020, Page 2 https://www.jacc.org/doi/10.1016/j.jacc.2020.04.027

Circulation

Limitations of Contemporary Guidelines for Managing Patients at High Genetic Risk of Coronary Artery Disease

(6–8) With accruing data on the population genetic determinants of CAD, and increased availability of both healthcare-associated and consumer-driven genetic testing - the latter now pursued by over 26 million individuals - a genetic predictor of CAD may serve as another risk-enhancing factor that is both broadly available and quantifiable early in life.(9)

A CAD "polygenic risk score" (PRS) captures the net, inherited susceptibility to CAD conferred by many common genetic variants as a single, quantitative risk factor following a normal distribution. PRS that quantify a genetic predisposition to CAD have been validated in multiple population-based cohorts.(10–12) Notably, ample data suggest that CAD PRS may identify subsets of the population more likely to benefit from lifestyle modifications and from statin therapy.(13–15),(16) More recently, the use of a genome-wide set of common genetic variants improved the prognostic capabilities of CAD PRS, particularly for identifying those with the highest genetic predisposition.(17) In addition, application of a genome-wide PRS to a large, population-based cohort demonstrated the potential discriminative benefit of a genome-wide CAD PRS when added to select clinical risk factors.(18)



SPECIAL ARTICLE

Clinical utility and implementation of polygenic risk scores for predicting cardiovascular disease

A clinical consensus statement of the ESC Council on Cardiovascular Genomics, the ESC Cardiovascular Risk Collaboration, and the European Association of Preventive Cardiology

Circulation

Volume 146, Issue 8, 23 August 2022; Pages e93-e118 https://doi.org/10.1161/CIR.000000000001077



AHA SCIENTIFIC STATEMENT

Polygenic Risk Scores for Cardiovascular Disease: A Scientific Statement From the American Heart Association

Jack W. O'Sullivan, Sridharan Raghavan, Carla Marquez-Luna, Jasmine A. Luzum, Scott M. Damrauer, Euan A. Ashley,

European Society of Cardiology (ESC) Policy Statement on Polygenic Risk Scores Q1.2025



CARDIO inCode - Polygenic Risk Score: Clinical utility

Primary Prevention:

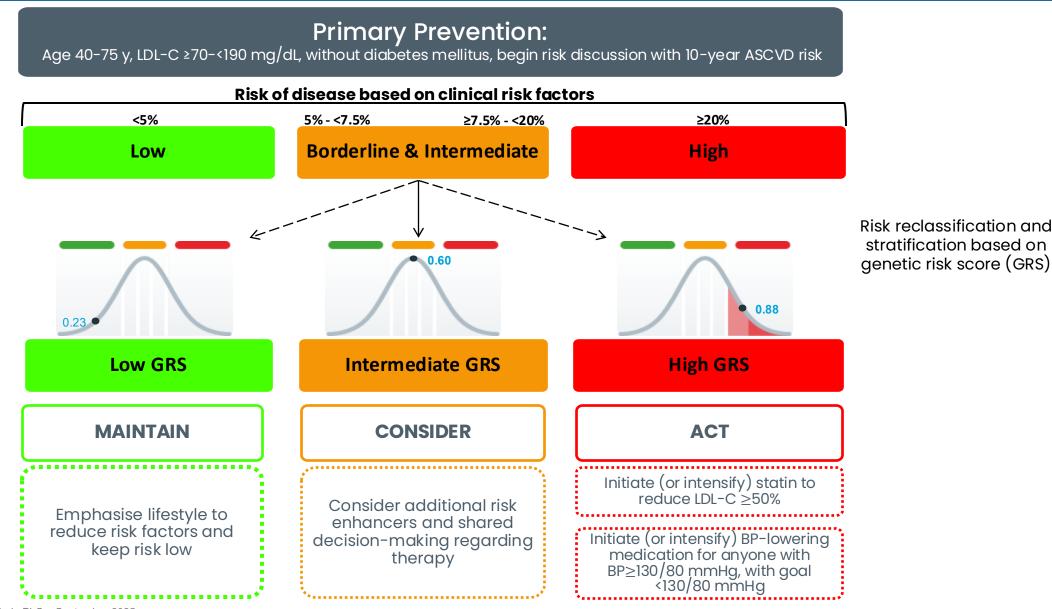
Age 40-75 y, LDL-C ≥70-<190 mg/dL, without diabetes mellitus, begin risk discussion with 10-year ASCVD risk

Risk of disease based on clinical risk factors

 <5%</td>
 5% - <7.5%</td>
 ≥7.5% - <20%</td>
 ≥20%

 Low
 Borderline & Intermediate
 High

CARDIO inCode - Polygenic Risk Score: Clinical utility



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 is the first 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 •

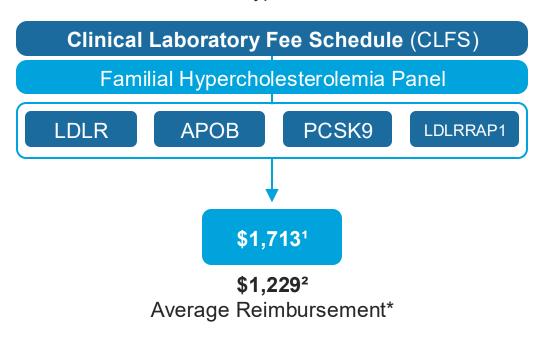
- Established ICD-10 and CPT Codes for FH Testing should enable rapid adoption of testing with targeted payers
 - Favourable reimbursement policies in place for FH testing with IDNs, regional, and national payers

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	
Clinically diagnosed FH: Estimated 200K Patients	0.2M¹	
ICD-10 code for Familial Hypercholesterolemia (FH)	0.2101	
These patients have not been tested for FH genetic variants		
Undiagnosed Probable FH		
Predictive modeling based on clinical features in US population	1.3M²	
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

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 partners 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







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% of this population have been genetically diagnosed in England
- UK NHS target is to detect 25% of FH population





UK Strategy: NHS Cardiovascular Disease Prevention Program - September 2025

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.

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.

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.

Health Innovation Network



::GENinCode

2,550 FH samples tested

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 – Introduction of LIPID inCode testing

NHS Long-Term Plan to improve FH diagnosis rates to at least 25% of FH patients lealth Innovation MEALTH MNOWE NEWC ICS wide Health Innovation Last Melands **3,162,000** – Population in Health Innovation East NE-AHSN Health Innovation WEST MIDLANDS **UCLPartners** 67 Primary Care Networks Health Innovation West of England @MINANE 37,944 FH Tests to Deliver 12,600 FH +ve Patients his 3,162 Patients Health Innovation Health Innovation Kent Surrey Susses (25% Target) Wessex

NHS: HIN's – Expansion to Prevention of CVD

NHS Long-Term Plan to improve FH diagnosis rates to at least 25% of FH patients Health Innovation HEALTH BRIOWERION **3,162,000** – Population in Health Innovation East * NE-AHSN Health Innovation WEST MIDLANDS UCLPartners 67 Primary Care Networks Health Innovation West of England 37,944 FH Tests to Deliver hin 12,600 FH +ve Patients 3,162 Patients (25% Target)

- Phased implementation of LIPID inCode to help achieve NHS targets
- Pharma collaborative discussions targeting patients 'most in need' of lipid lowering medications
- Focus on PCSK9 inhibitors and new therapies

Wessex

EU Strategy

- First half revenue growth driven by CARDIO inCode regional roll-out 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 Basque Country, Madrid and Andalucia regions
- Growth via strategic alliance for CARDIO inCode, THROMBO inCode and LIPID inCode
 - Synlab-Spain Collaboration in IVF Clinics but also building alliances in Mexico
 - Synlab-Mexico Building alliances in cardiovascular clinics
 - Longwood Public healthcare product implementations
- 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
 - CARDIO inCode growth supported by agreement with a health insurance provider
- Strengthening LIPID inCode sales in Germany with Uniklinikum (based on NHS model)





The ROCA test recommended in NICE Guidance



- Risk of Ovarian Cancer Algorithm (ROCA) test. 'First in class' risk assessment for early detection of ovarian cancer
- New 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
- Targeting roll out in 6 regions supported by local Cancer Alliances SAS model 'Kick start' funding secured for 850 tests (238 patients) at 2 North London Cancer Alliance regions
- Recurring revenue: 1 patient for 5 years surveillance = £1,500; 10 years surveillance = £3,000

Europe

- Switzerland (Genesupport.ch) and Austria (Ordensklinikum) now live.
- First tests received Dec 2024; Working with partners to assist marketing efforts.

NHS TAM: based on prevalence of BRCA mutations in female population of England and Wales which = **0.3**%

18M women in England and Wales over 35y

Number eligible for **ROCA test = 54,000**

Evidence shows **40%** of women choose to defer preventive surgery = **21,600**

21,600 X £300/Yr = **£6.4m**

1. NICE Guidance: Overview | Ovarian cancer: identifying and managing familial and genetic risk | Guidance | NICE



2025 Interim Report (Unaudited)

First half revenues £1.6M, 15% year-on-year growth

Gross Profit margin increased to 53% (2024: 52.6%) reflecting improving geographic margin mix from UK and US.

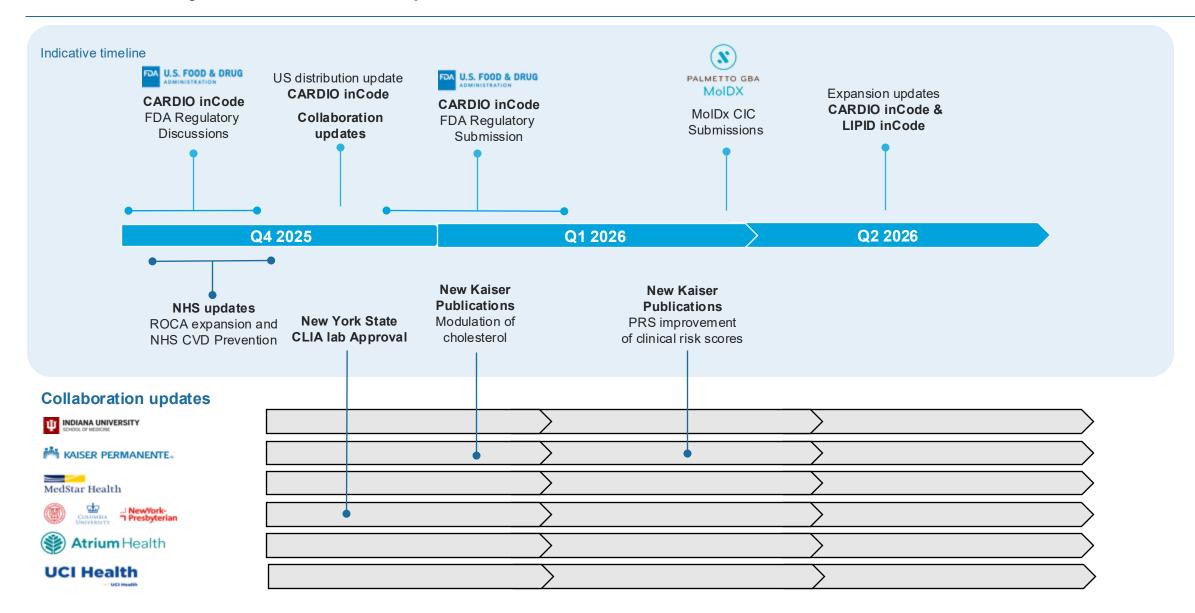
Adjusted EBITDA loss £2.0M (2024: £2.0M). Excludes unrealised foreign exchange loss of (£0.5m).

Comprehensive loss of £2.5M reflecting growth in revenues, margin and contained operating costs.

Cash balances - £2.4M at end June 2025 (2024: End Dec £1.1M). Net fundraising proceeds of £3.7M completed in March 2025.



2025/26 Key events and expected newsflow



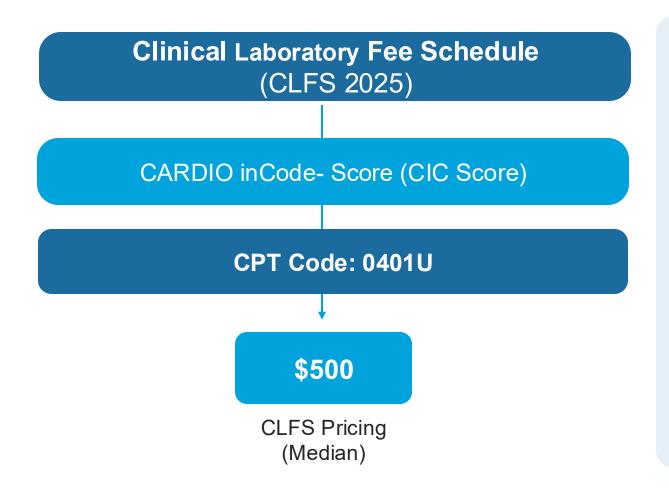
Summary and outlook

- Significant year-on-year revenue growth, but slower than expected partly due to NHS restructuring. The delays mean revenue for the full year is likely to be lower than expected, with full year revenue now estimated to be £3.3m with similar levels of cost in the second half
- Commercial expansion of LIPID inCode and CARDIO inCode across the US, EU and UK markets
- Progression of CARDIO inCode-Score De Novo submission for FDA approval to accelerate US sales
- Complete discussions with US commercial partners for CARDIO inCode-Score test distribution
- Expansion of the MVZ Uniklinikum, Germany collaborative programme
- Expansion of CARDIO inCode® pilots in Catalonia, Extremadura and introduction to other Spanish regions
- Expand ROCA commercial program with the NHS and European partner
- Drive to breakeven over the medium term





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 MolDx) 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 (based on physicians interviewed)	Patients in Target Segment	No. Likely to get Prescription
Intermediate Risk ¹ Patients inadequately controlling risk e.g., not taking statins or making lifestyle changes (estimated 33% of intermediate-risk patients) ³	9M	4.4M
Low Risk ¹ 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.} Moone singhe, Ramal et al. "Prevalence and Cardio vascular 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: ASCVD - ACC/AHA Guidelines & Risk Enhancing Factors

Amett et al

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

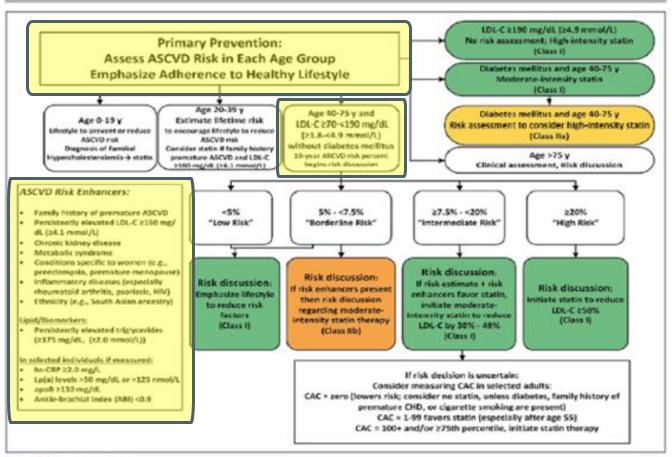


Figure 3. Primary prevention.

Colors correspond to Class of Recommendation in Table 1. ABI indicates ankle-brachial index; apo8, apolipoprotein B; ASCVD, atherosclerotic cardiovascular disease; CAC, coronary artery calcium; CHD, coronary heart disease; HIV, human immunodeficiency virus; hs-CRP, high-sensitivity C-reactive protein; LDL-C, low-density lipoprotein cholesterol; and Lp(a), lipoprotein (a). Reproduced with permission from Grundy et al. M.3.1 Copyright © 2018, American Heart Association, Inc., and American College of Cardiology Foundation.



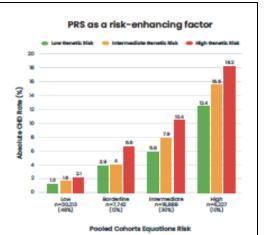
CARDIO inCode: Recent Clinical Publications

- 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.

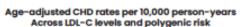




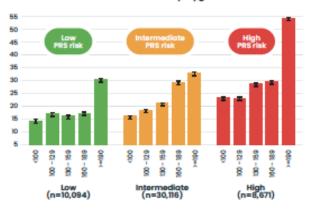
- Polygenic risk and incident coronary heart disease in a large multiethnic cohort: Iribarren et al., American Journal of Preventive Cardiology 2024;18:100661
- CARDIO inCode-Score PRS is independently associated with an increased (lifetime) risk of incident CHD
- PRS and incident CHD was consistent 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.



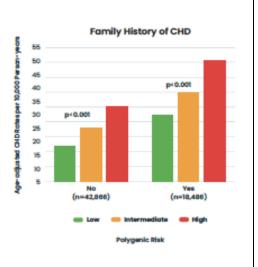
- Joint consideration of LDL-C and polygenic risk for incident coronary heart disease in a multi-ethnic cohort of 48,881: ESC Preventive Cardiology, Athens, April 2024
- Chart shows that subjects with high polygenic risk should not have LDL-C levels above 130 mg/ dL as their CHD risk is similar to those with LDL-C levels =>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.



Control Broup is 0 feverable Ura, by Benedic Mak (PES).



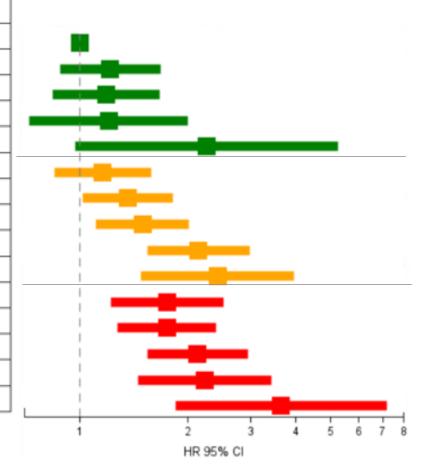
- Interplay between Family History and Polygenic Risk for Coronary Heart Disease: A Cohort Study among over 60 thousand Individuals: ESC Annual Congress, London, 2nd September 2024
- PRS and family history CHD are positively correlated, and both independently contribute to risk of incident CHD
- 42% 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.



The effect of LDL-C is modulated by CHD PRS

PRS Group	LDL-C (mg/dL)	CHD cases / Total individuals	Age-adjusted rate per 10,000 person-years (SE)	Adjusted* HR (95% CI); p-value
Low PRS	<100	52/2,296	14.3 (SE)	1 [Reference]
	100-<129	122/4,005	17.2	1.21 (0.88-1.68); 0.25
	130-<159	85/2,720	16.8	1.19 (0.84-1.67); 0.33
	160-189	21/710	16.5	1.20 (0.72-2.00); 0.48
	≥190	6/115	31.7	2.26 (0.97-5.26); 0.06
Int PRS	<100	166/6,690	16.4	1.16 (0.85-1.58); 0.36
_	100-<129	397/11,980	18.8	1.36 (1.02-1.81); 0.04
	130-<159	310/8,107	20.6	1.50 (1.11-2.01); 0.01
	≥160-189	108/2,125	29.1	2.14 (1.54-2.98); <0.001
	≥190	23/402	32.2	2.42 (1.48-3.96); <0.001
High PRS	<100	71/1,857	24.0	1.75 (1.22-2.51); 0.002
	100-<129	143/3,395	24.1	1.75 (1.27-2.40); <0.001
	130-<159	128/2,399	29.4	2.12 (1.54-2.94); <0.001
	160-189	36/664	29.7	2.22 (1.45-3.41); <0.001
	≥190	10/111	50.7	3.64 (1.85-7.16); <0.001

^{*} Age, sex, 5 principal components of genetic ancestry, BMI, smoking and hypertension.



Appendices: P&L

GENinCode plc	H1 2025	H1 2024	+/-	Full Yr 2024
	£'000	£'000	£'000	£'000
Revenue	1,602	1,389	213	2,701
Cost of sales	(753)	(659)	(94)	(1,275)
Gross profit	849	730	119	1,426
GM %	53%	53%	0%	53%
Admin expenses (excluding forex)	(2,918)	(2,784)	(134)	-5,657
AEBITDA	(2,069)	(2,054)	(15)	(4,231)
Depreciation/Amortisation	(162)	(172)	10	(347)
Share based payments	(266)	(143)	(123)	(397)
Unrealised currency gain(loss) from translation	(473)	(106)	(367)	(216)
Impairment profit/(loss)	-	-	-	(149)
Reversal of contingent consideration provision	-	<u>-</u>	-	206
Operating Loss	(2,970)	(2,475)	(495)	(5,134)
Other Income	25	61	(36)	99
Finance Charge	(22)	(23)	1	(48)
Loss Before Income Tax	(2,967)	(2,437)	(530)	(5,083)
Income Tax	4	8	(4)	649
Loss for the Financial Period	(2,963)	(2,429)	(534)	(4,434)
Exchange diff on translation of foreign ops	500	68	432	132
Loss attributable to equity shareholders	(2,463)	(2,361)	(102)	(4,302)

Appendices: Balance Sheet

OFNin Code who	H1 2025	H1 2024	+/-	Full Year 2024
GENinCode plc	£'000	£'000	£'000	£'000
Assets				
Non-current assets				
Intangible assets	108	128	(20)	118
Property, plant & equipment	120	305	(110)	234
Right of use asset	166	242	(76)	207
Goodwill	-	149	(149)	-
Total non-current assets	394	824	(355)	559
Current assets				
Inventory	95	79	16	126
Trade and other receivables	1,229	805	527	813
Financial assets	65	38	27	55
Cash and cash equivalents	2,438	2,915	(476)	1,110
Total current assets	3,827	3,837	94	2,104
Total assets	4,221	4,661	(261)	2,663
Equity Shareholders' Equity				
Share capital	2,869	1,770	1,099	1,770
Share premium	21,126	18,482	2,644	18,483
Other reserves	1,576	502	1,143	820
Retained deficit	(22,908)	(17,940)	(4,859)	(19,946)
Total equity	2,663	2,814	27	1,127
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Liabilities				
Non-current liabilities				
Lease liability	191	180	11	147
Contingent consideration	-	191	(191)	-
Current liabilities				
Trade and other payables	1,360	1,378	(17)	1,290
Lease liability	-	81	(81)	87
Deferred tax	7	17	(10)	12
Total liabilities	1,558	1,847	(288)	1,536

Appendices: Cash Flow Statement

GENinCode plc	H1 2025 £'000	H1 2024 £'000	+/- £'000	Full Year 2024 £'000
Loss before taxation	(2,968)	(2,437)	(421)	(5,083)
Adjustments	413	277	57	636
Operating Loss before working capital changes	(2,555)	(2,160)	(364)	(4,447)
Working capital changes	(660)	(1,229)	732	(726)
Net cash outflow from operating activities	(3,215)	(3,389)	368	(5,173)
Investing activities	25	60	(35)	50
Financing activities	3,678	3,696	(18)	3,645
Net increase in cash and cash equivalents	488	367	315	(1,478)
Cash and cash equivalents at beginning of period	1,110	2,484	(1,374)	2,484
Exchange gains / (losses) on cash and cash equivalents	840	64	583	104
Cash and cash equivalents at end of period	2,438	2,915	(476)	1,110

