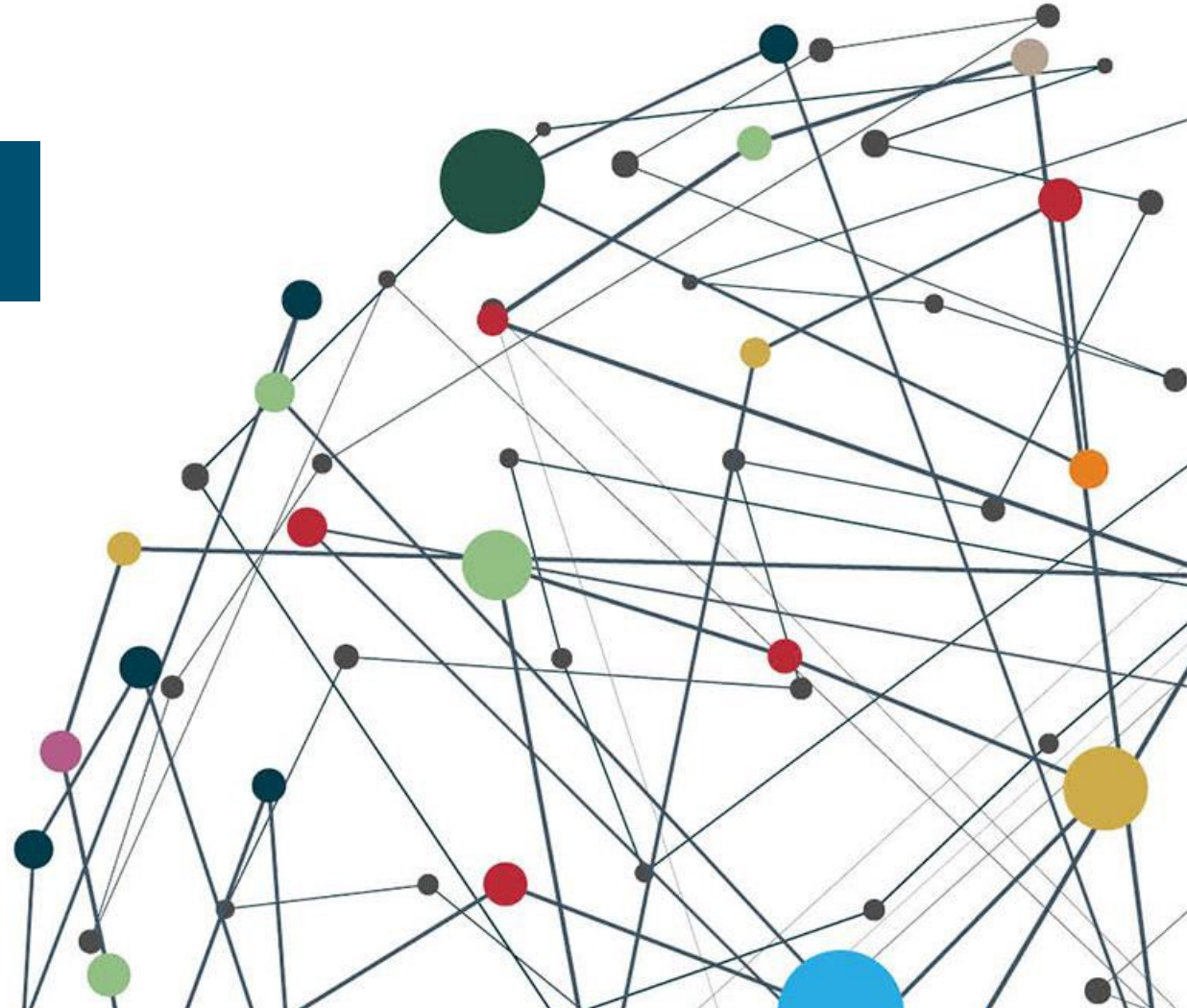
Advancing Pharmacogenetic Testing to the point-of-care

Interim Results:
31 December 2023



5 April 2024

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genedrive plc (LSE : GDR): Executive team

James Cheek | Chief Executive Officer

- Appointed in September 2023
- Over 20 years of commercial and operational experience in a variety of diagnostic fields.
- Prior roles with Roche, Beckman Coulter and Cepheid. Former Board Executive at BIVDA, BIVDA representative to the NHS Supply chain Board, Chair of the BIVDA procurement working party.

Russ Shaw | Chief Financial Officer

- Appointed in April 2022
- Over 25 years of international experience across multiple sectors including life-sciences, technology and the industrials.
- 10 years as Finance Director at Driver Group plc, an AIM quoted company operating in the engineering and construction industry.
- CFO of several private companies in recent years and is a qualified Accountant and Treasury professional.

Dr Gino Miele | Chief Scientific Officer

- Appointed to board as CSO September 2023
- Considerable experience in the translational genomics and development of molecular diagnostic technologies and systems. Has held position of R&D Director at genedrive since 2015 and its predecessor Epistem since 2011.
- Key driver in the development of the genedrive® system and the recent menu of pharmacogenetic tests.

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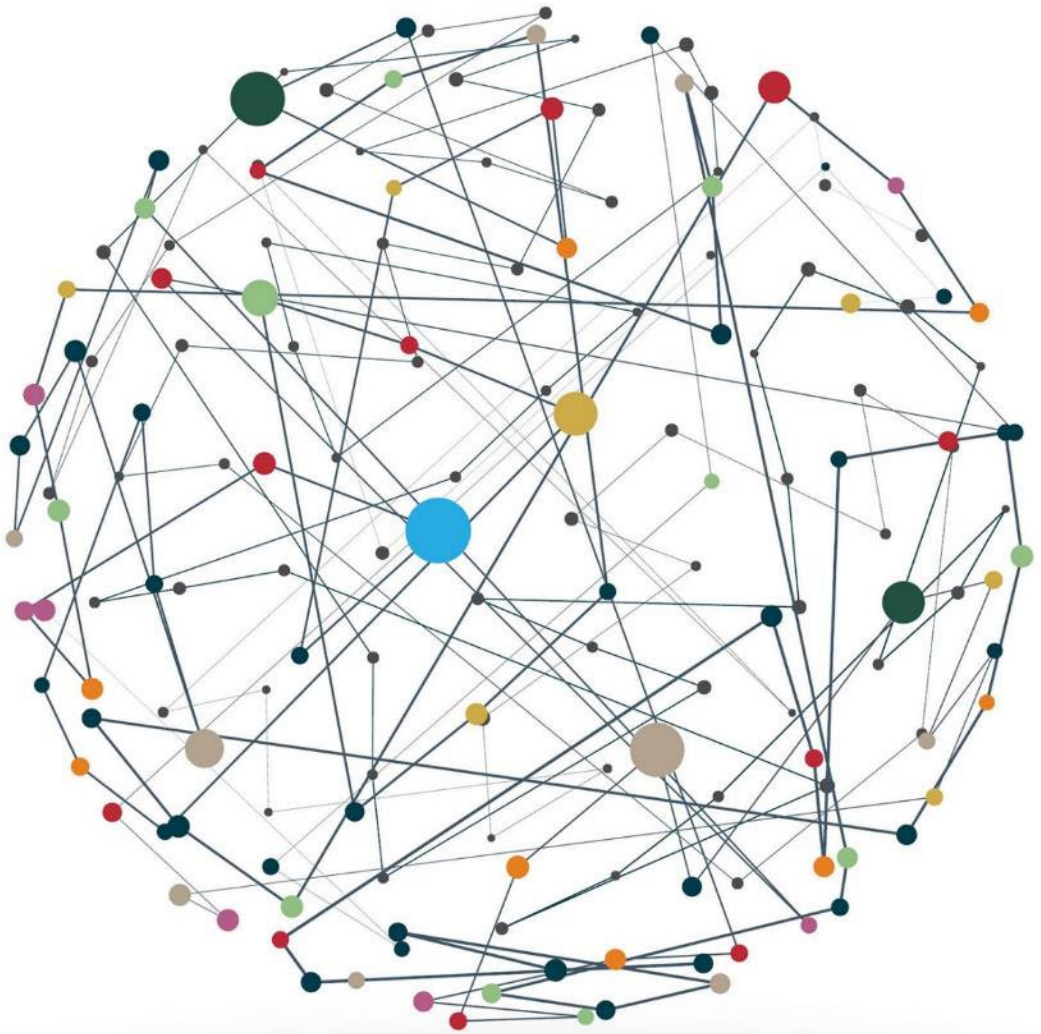
Agenda

1. What we do
2. Product Development
3. MT-RNR1
4. CYP2C19
5. Summary Financials
6. News flow summary



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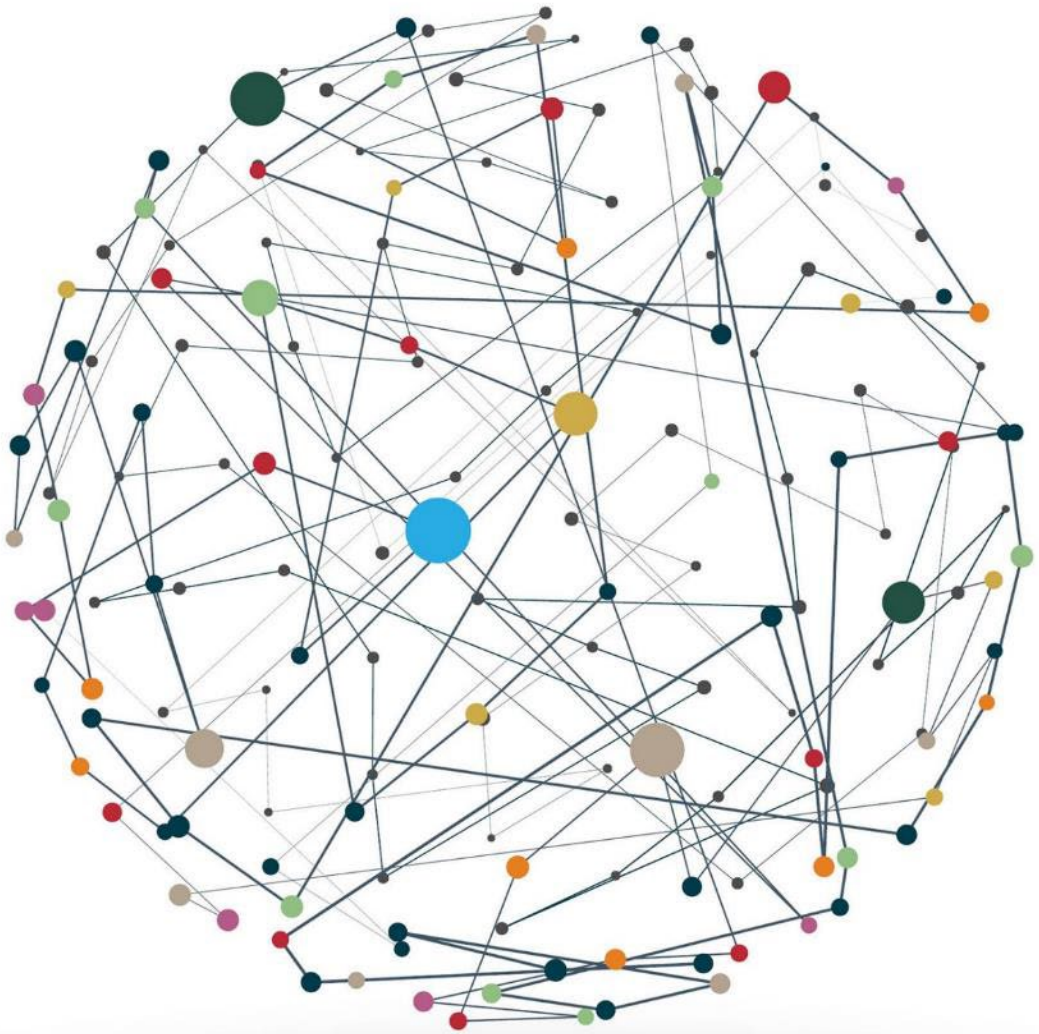
What we do



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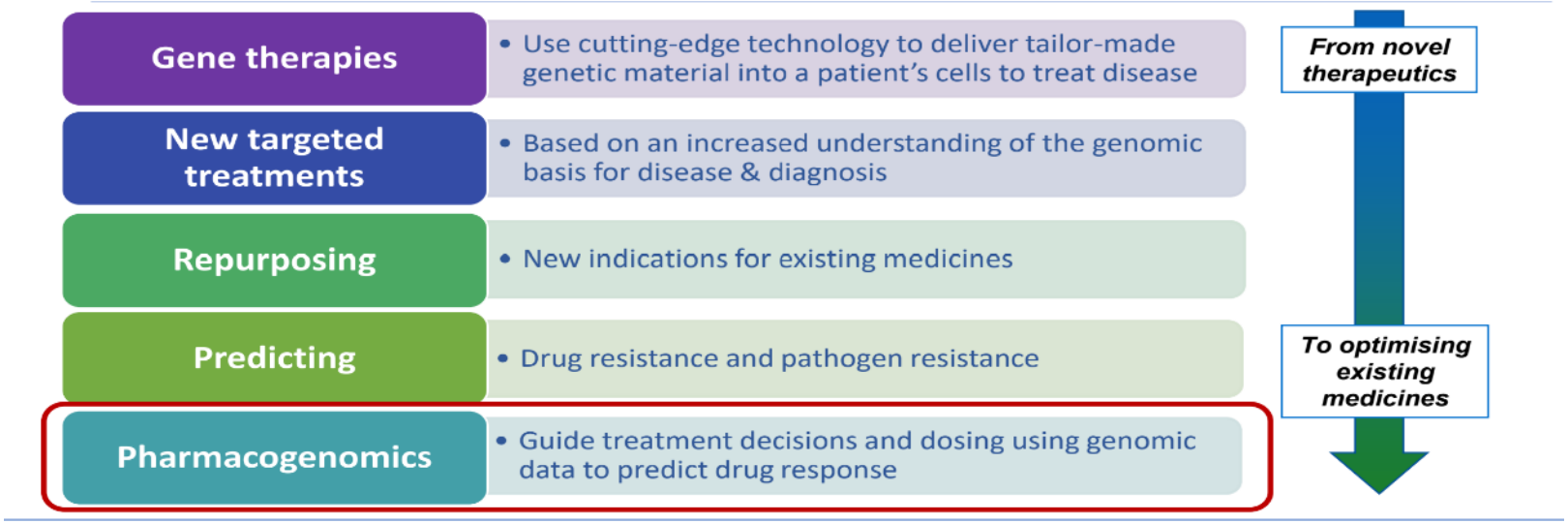
Where are we positioned in relation to Genomics use for precision treatments ?



Genetic variants in an individual can dictate the likelihood that a drug will be effective or not, or cause unintended harm through an adverse reaction.

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The use of Pharmacogenetic testing is gaining pace : -

In the UK NHS alone –

- Expanding genetic tests within the national genomic testing directory
- Licensing of medicines with pharmacogenetic guided dosing
- NICE guidelines and assessments
- Professional body guidelines and recommendations for practice
- Core to UK NHS Genomics 5-year strategy[1]

Genomics & diagnostics are key in the healthcare shift towards personalised medicines, improving patient outcomes & reducing costs.

1 NHS England » Genomics strategy

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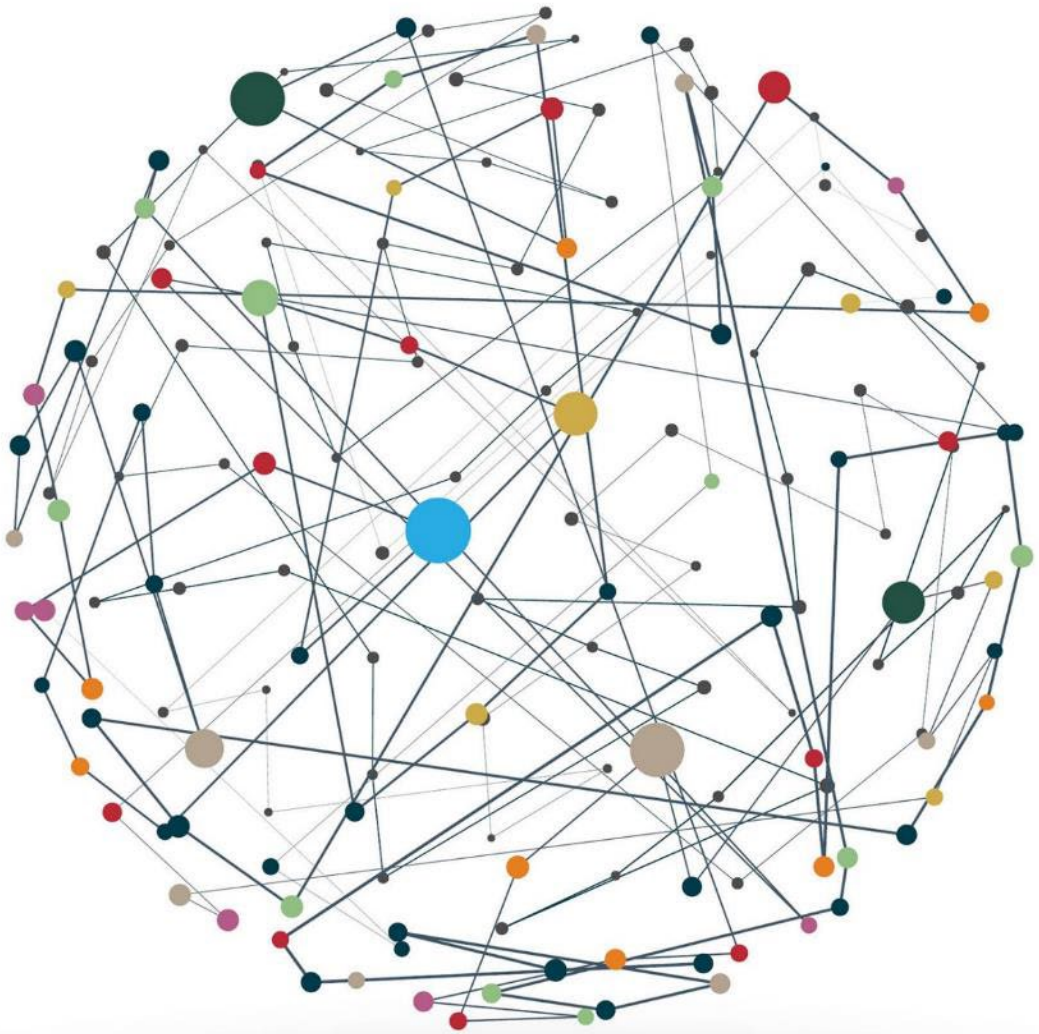
Genedrive®
Product Development status



Genedrive® System

- Low cost, rapid, touchscreen operated thermocycler
- Permitting sample to result in ~26mins (MT-RNR1) & ~70mins (CYP2C19)
- Positioned outside of core laboratories, at point-of-care in emergency healthcare paradigms
- Proprietary core chemistry;
  - No requirement for sample preparation (nucleic acid extraction)
  - No requirement for cold chain logistics for transport or use
- Electronic patient record integration

MT-RNR1 ID (AIHL - Antibiotic Induced Hearing Loss)

MT-RNR1 GD ID Kit

NICE National Institute for Health and Care Excellence

Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies: early value assessment

Health technology evaluation
Published: 30 March 2023

NICE National Institute for Health and Care Excellence

Evidence-generation plan for Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies

Published: 10 August 2023

NIHR | National Institute for Health and Care Research

Office for Life Sciences — Real World Evidence Programme

- World's first point of care pharmacogenetic test for AIHL in NICU settings
- NICE recommendation for use in NHS whilst further evidence generated
- NICE evidence generation requirements published
- NIHR/OLS funding application for consortia led programmes to address NICE EVA requirements submitted (1st Oct.'24 start date if successful)
  - 18-month programme duration, including 14 hospital sites of different tier settings across the UK
  - Submission to NICE to seek change in guidance from conditional to full can be made earlier as soon as evidence is generated

MT-RNR1 ID (AIHL - Antibiotic Induced Hearing Loss)

MT-RNR1 ID Kit

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Office for Life Sciences

Real World Evidence Programme

- No predicate test in USA for this paradigm
  - Unique challenges associated with this required interaction with FDA on how to generate evidence & what would be viewed as satisfactory
- FDA expectations for evidencing performance & safety clear, with *de novo* submission route to be pursued.
  - Required US Clinical group partner in final contractual stages
  - International Biomedical contracted as US distributor
  - Anticipated start in late 2024 (subject to funding)

CYP2C19 ID

CYP2C19 ID Kit

- Only known point of care test that identifies **six** DNA variants in the CYP2C19 gene that are responsible for ineffective metabolism of the drug Clopidogrel
- Some of these variants whilst rare in general population are higher frequency in certain ethnic groups
- NICE recommend CYP2C19 genotyping in IS/TIA within 24hrs prior to administration of clopidogrel
  - Preliminary draft recommendation of Genedrive CYP2C19 test for point of care testing in NHS (Final guidance to be issued in July)
    - ✓ *Maximal ethnicity coverage*
    - ✓ *No requirement for fridges and freezers*
    - ✓ *Electronic health record integration*
    - ✓ *Dominant cost effectiveness in health economic modelling*

NICE National Institute for Health and Care Excellence

CYP2C19 genotype testing to guide clopidogrel use after ischaemic stroke or transient ischaemic attack In development [GID-DG10054]Expected publication date: 10 July 2024

CYP2C19 ID

CYP2C19 ID Kit

NICE National Institute for Health and Care Excellence

CYP2C19 genotype testing to guide clopidogrel use after ischaemic stroke or transient ischaemic attack In development [GID-DG10054]Expected publication date: 10 July 2024

- NICE UK guidance is for CYP2C19/Clopidogrel use in IS/TIA
  - Clopidogrel ranked #37 in top drug use in US in 2021 (includes non-IS/TIA), with 4.2M patients & 17M prescription events[1]
- Non-clopidogrel alternative (Ticagrelor) whilst not impacted by CYP2C19 is more expensive, has increased bleeding risks and does not have marketing authorisation for use in preventing further TIA or strokes in the UK[2]
- UKCA certified, permitting UK commercialisation
- Innovate funded DEVOTE programme for clinical validation is underway and once completed UK commercialisation efforts will commence
  - Also generates data required for submission for CE-IVD certification (early 2025) and non-UK commercialisation

[1] Clopidogrel - Drug Usage Statistics, ClinCalc DrugStats Database

[2] (nice.org.uk)

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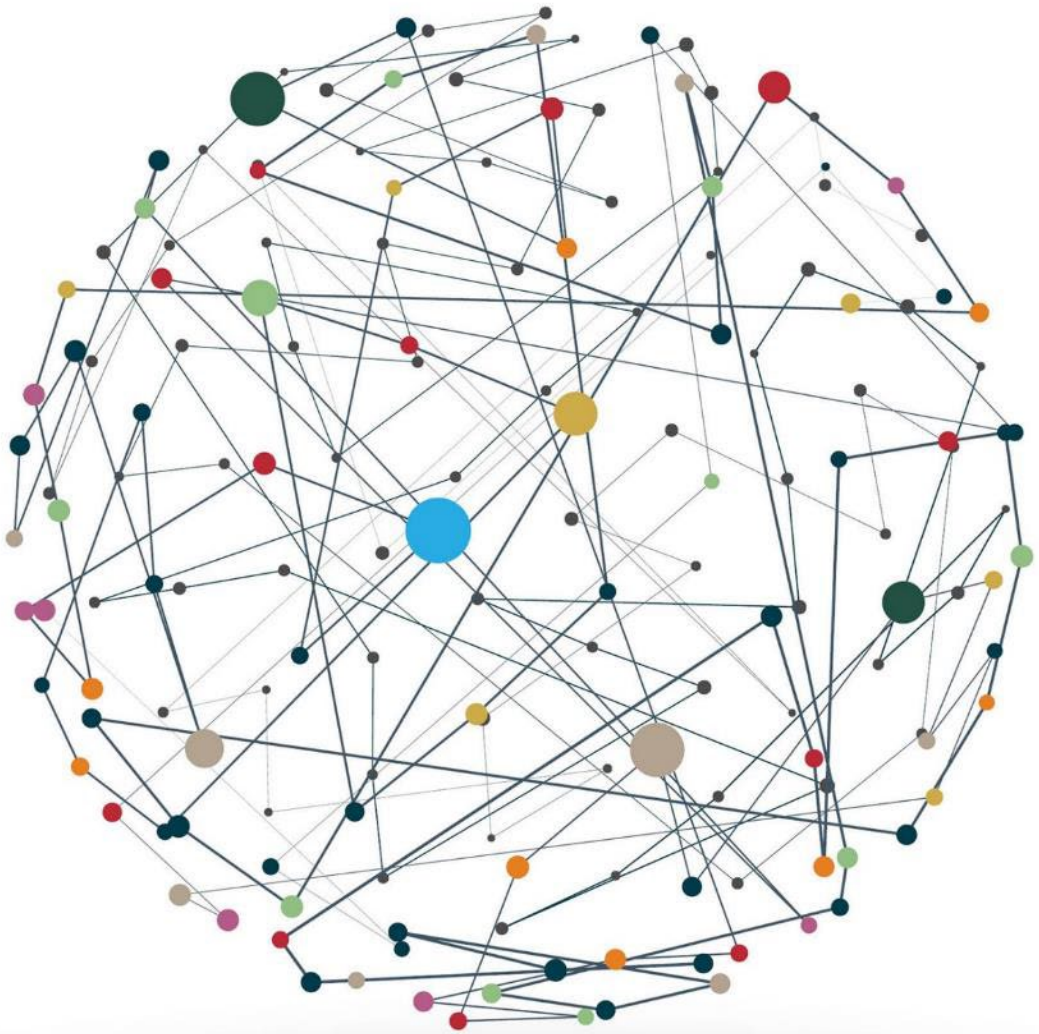
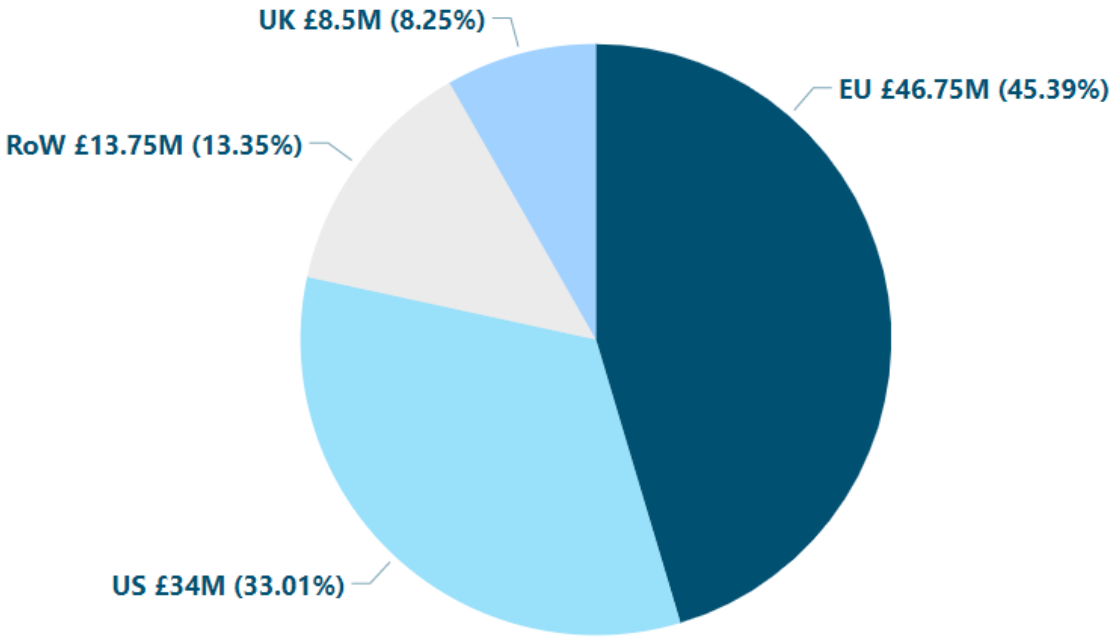
Genedrive®
MT-RNR1 ID Kit

Antibiotic Induced Hearing Loss (AIHL)



AIHL - Antibiotic Induced Hearing Loss

Total Addressable Market Estimate = £100M



Model assumptions:
- International - Extrapolated from population sizes, birth rates, and UK admission to NICU rate
- Based direct sale model

Approximately 100K UK NICU admissions

Addressable Global Market >£100m

CE-IVD Certified

Positive Health Economic Case in place and being developed

NICE recommendation (conditional) NICE EVA evidence generation plan

Final stage contractual process for strategic partner & distributor in US for FDA submission process

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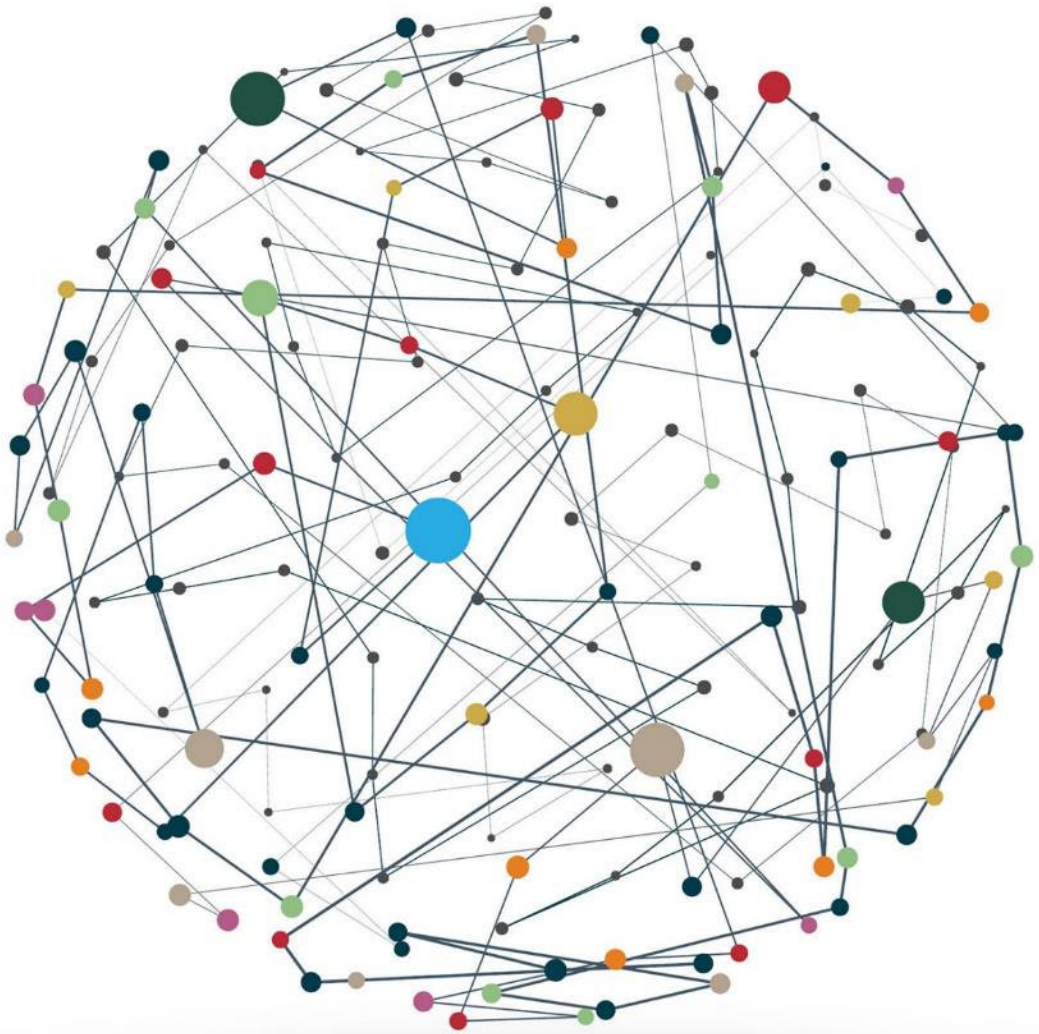
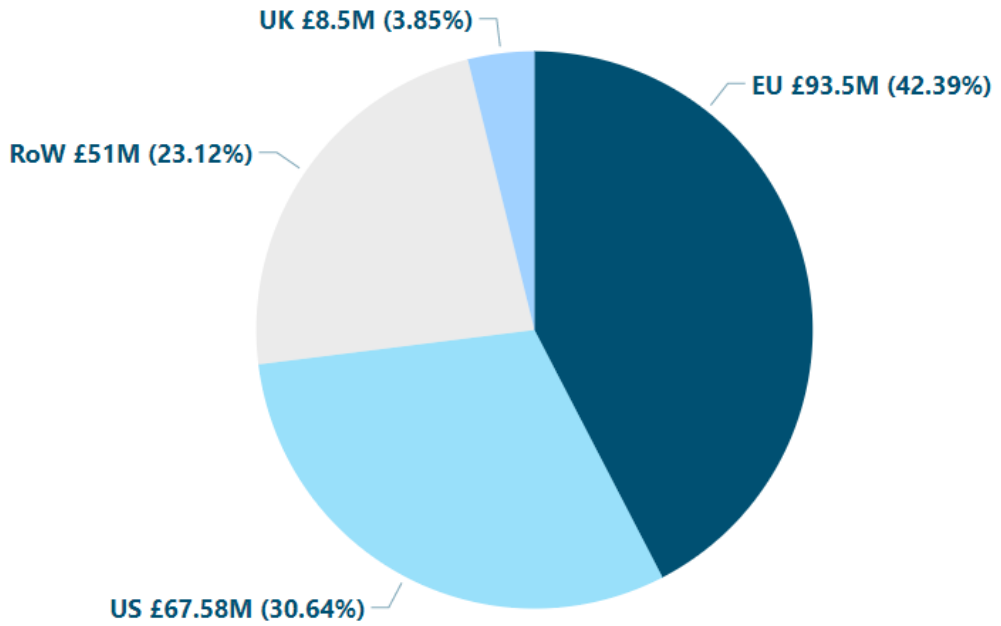
Genedrive® CYP2C19-ID Kit



are Company estimates

Genedrive® CYP2C19-ID Kit

Total Addressable Market Estimate = £220M



Model assumptions:
- UK - Based on NICE prevalence of stroke
- International – Europe AHA journals USA – CDC
- Row – assumes <10% developed healthcare markets

Addressable Market for ischemic strokes.

100K strokes per year in the UK

~30,000 UK patients could get better health outcome

Collaboration under Innovate funded DEVOTE program, saving >£1m in validation costs for CE-IVD

Full NICE recommendation (draft) for use in NHS

DEVOTE clinical study (UK) underway

Market

- ~12 million strokes per year globally[1]
  - ~100,000 per year in UK
  - ~38,000 stroke related
- Stroke incidence per annum in the UK predicted to increase by 60% between 2015 and 2035[2]
- In an estimated 30% of patients, some antiplatelet drugs prescribed for stroke management are ineffective
- Pharmacogenetic/Pharmacogenomic testing is mainly performed in labs on expensive equipment but the advance of point of care testing is changing this due to the speed and closeness to the patient
  - UK minimum result turnaround time from Genetic hubs 2 days with averages far higher
- There are currently only 7 genomic hubs in England – NICE guidance for CYP2C19 testing in IS/TIA is 24 hours

[1] PowerPoint Presentation (world-stroke.org)
[2] https://doi.org/10.1093/ageing/afz163

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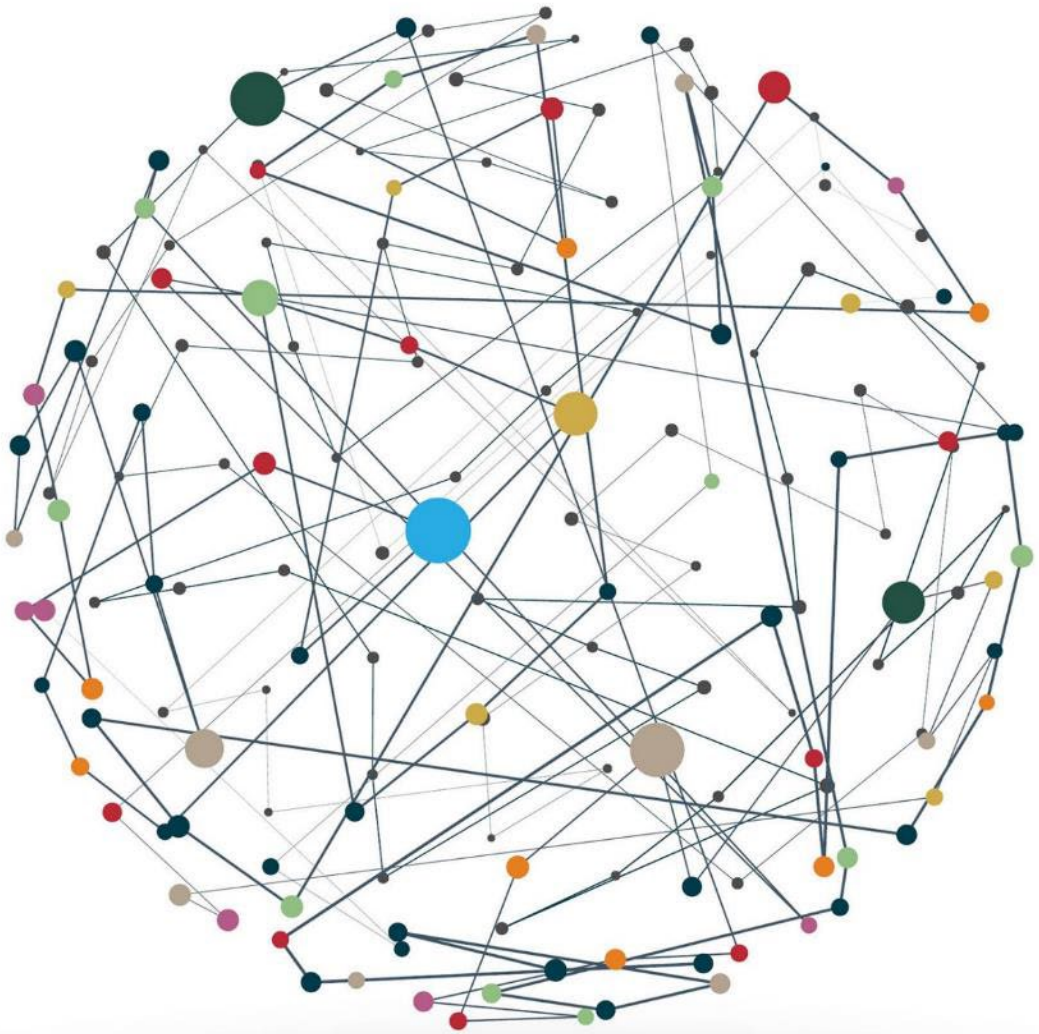
Summary Financials



Summary Financials - Income statement

Income statement	Dec-23 (6 months) £'000	Dec-22 (6 months) £'000	Jun-23 (12 months) £'000
Revenue and other income	238	21	55
R&D costs	(1,876)	(1,988)	(3,924)
Admin costs	(721)	(713)	(1,355)
Operating loss	(2,359)	(2,680)	(5,224)
Finance costs	(30)	(11)	(757)
Loss before tax	(2,389)	(2,691)	(5,981)
Tax	350	500	831
Loss after tax	**(2,039)**	**(2,191)**	**(5,150)**

- Revenue and other income increased >£0.2m
- R&D spend reduced £0.1m as we focused on near-commercialisation product development
- Admin costs at similar levels due to continued tight cost management
- Tax credit reflects reduction in HMRC R&D tax relief rates

Summary Financials – Cashflow

Cashflow	Dec-23 (6 months) £'000	Dec-22 (6 months) £'000	Jun-23 (12 months) £'000
Operating loss before changes in working capital	(2,201)	(2,533)	(4,874)
Working capital	(217)	126	113
Taxation	-	-	956
Net cashflow from operations	(2,418)	(2,407)	(3,805)
Proceeds from investment funding	1,200	-	2,300
Transaction costs - investment funding	(48)	-	(283)
Other	(109)	(99)	(200)
Net cash flow	(1,375)	(2,506)	(1,988)
Cash at bank b/f	2,601	4,589	4,589
Cash at bank c/f	**1,226**	**2,083**	**2,601**
Underlying monthly burn rate:	(421)	(418)	(413)

- Operating loss before changes in working capital is £0.3m less than H1-23 due to increased income and reduced costs
- Working capital consumed £0.2m related mainly to movement in creditors
- £1.2m received from the Investor Placing Agreement
- Unaudited cash at 20 March 2024 of £1.2m, following £0.8m receipt of R&D tax credit
- Underlying cash consumption of c£0.4m
- Cash runway remains as set out in interim results

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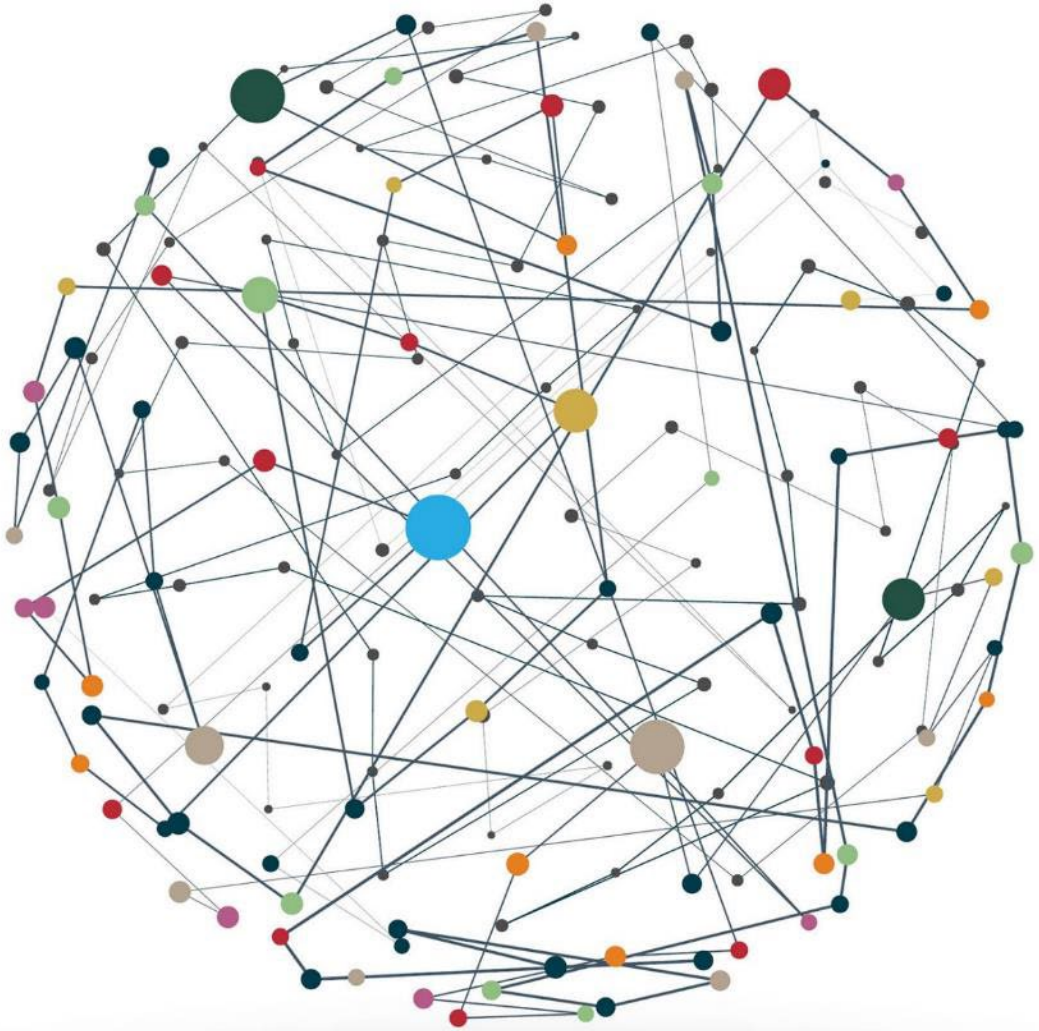
News flow summary



News flow summary

Near Term

- Revenue from additional go-live sites in the UK and abroad for MT RNR1
- Continue progressing special commissioning for MT RNR1
- Finalise position for FDA registration requirements for MT RNR1
- Further NICE data gathering for full recommendation commences MT RNR1
- Completion of DEVOTE clinical study for CYP2C19 for CE-IVDR accreditation
- Start UK Sales and Marketing activity for CYP2C19 and research use only sales outside the UK.
- Continuation of instrument design improvements to facilitate adoption, and expansion of test menu expansion
- Future funding activities to support FDA studies/regulatory review, product development and expected growth

Medium to Long Term

- Commence IVDR registration for CYP2C19 (~July 2024), expectation of CE-IVD approval (early 2025)
- Launch of CYP2C19 in non-UK territories following CE-IVD certification
- Commence FDA registration for MT RNR1
- Commence business cases for future target pipeline tests