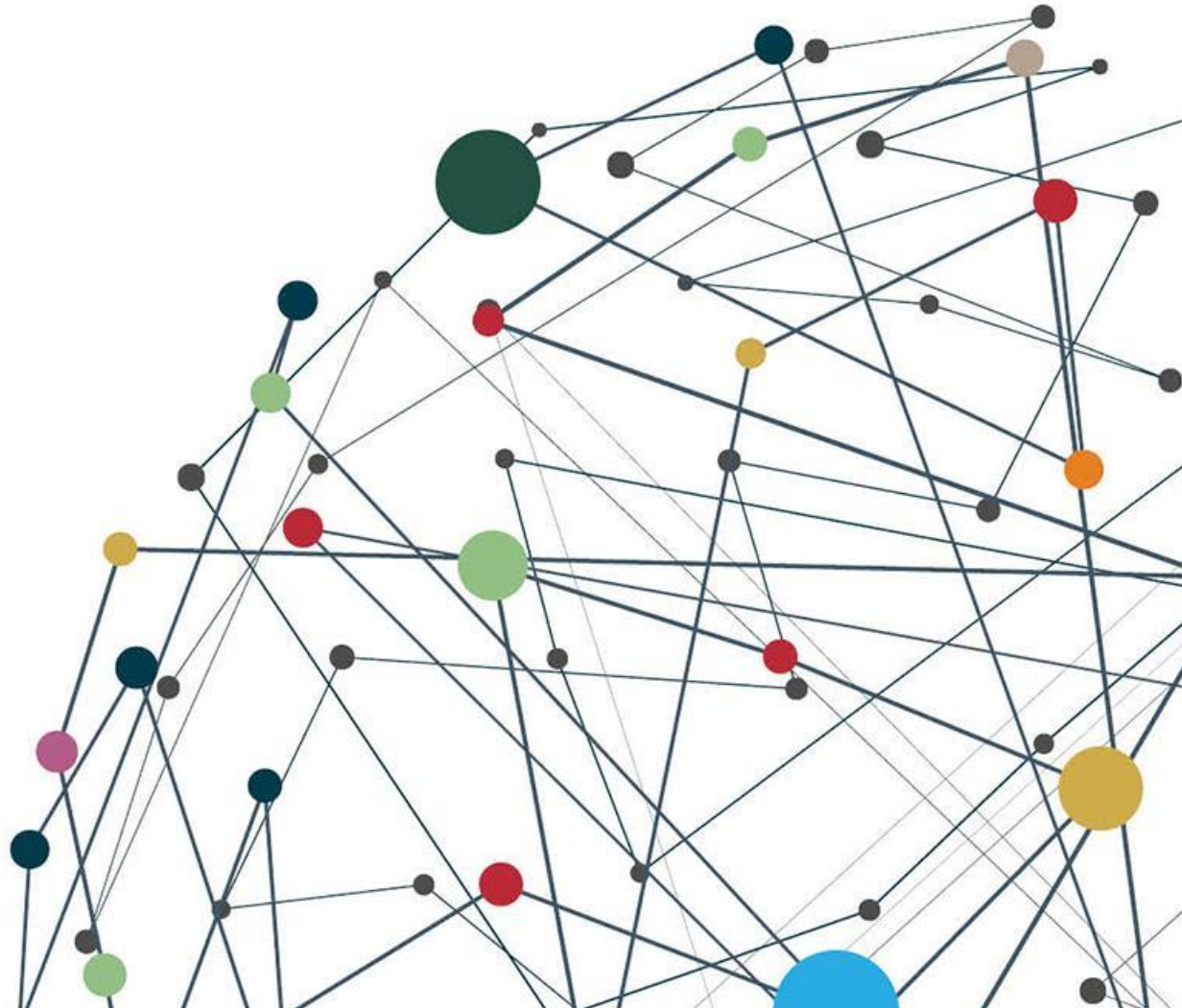

Advancing Pharmacogenetic Testing to the **point-of-care**

Year End Results:
30 June 2023

30 November 2023

genedrive



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, Chairman 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 September 2023.
- Considerable experience in the development of molecular diagnostic technologies and systems. Has held position of R&D Director at genedrive since 2015 and its predecessor Epistem since 2011.
- Prior to that Gino served as Associate Director for clinical translational genomics at Wyeth and Pfizer.
- Key driver in the development of the genedrive® system and the recent menu of pharmacogenetic tests.

genedrive plc (LSE : GDR): Who and What

- The Genedrive® device is a low-cost, rapid, simple-to-use point-of-care molecular diagnostic device.
- Our focus is increasingly on emergency medicine applications because the rapid delivery of actionable genetic information is a key strength of our patented technology & expertise.
- We have developed the world's first point of care pharmacogenet test to help avoid Antibiotic Induced Hearing Loss, and a have a new test available for improving health outcomes in stroke patients.
- NICE EVA conditional recommendation to use our MT-RNR1 test in the NHS. Further evidence required as part of EVA process to lead to full recommendation.
- NICE expected to recommend CYP2C19 genotyping for clopidogrel treatment in Ischaemic stroke patients in early 2024 when their paper on this is due to be published.
- Considering using the FDA break through device program for MT RNR1 test.



Why Pharmacogenetics?

Medications can **work differently** for everyone

Some patients may have an unintended, harmful response, known as an **Adverse Drug Reaction (ADR)**



PGx could prevent up to

30%

ADRs

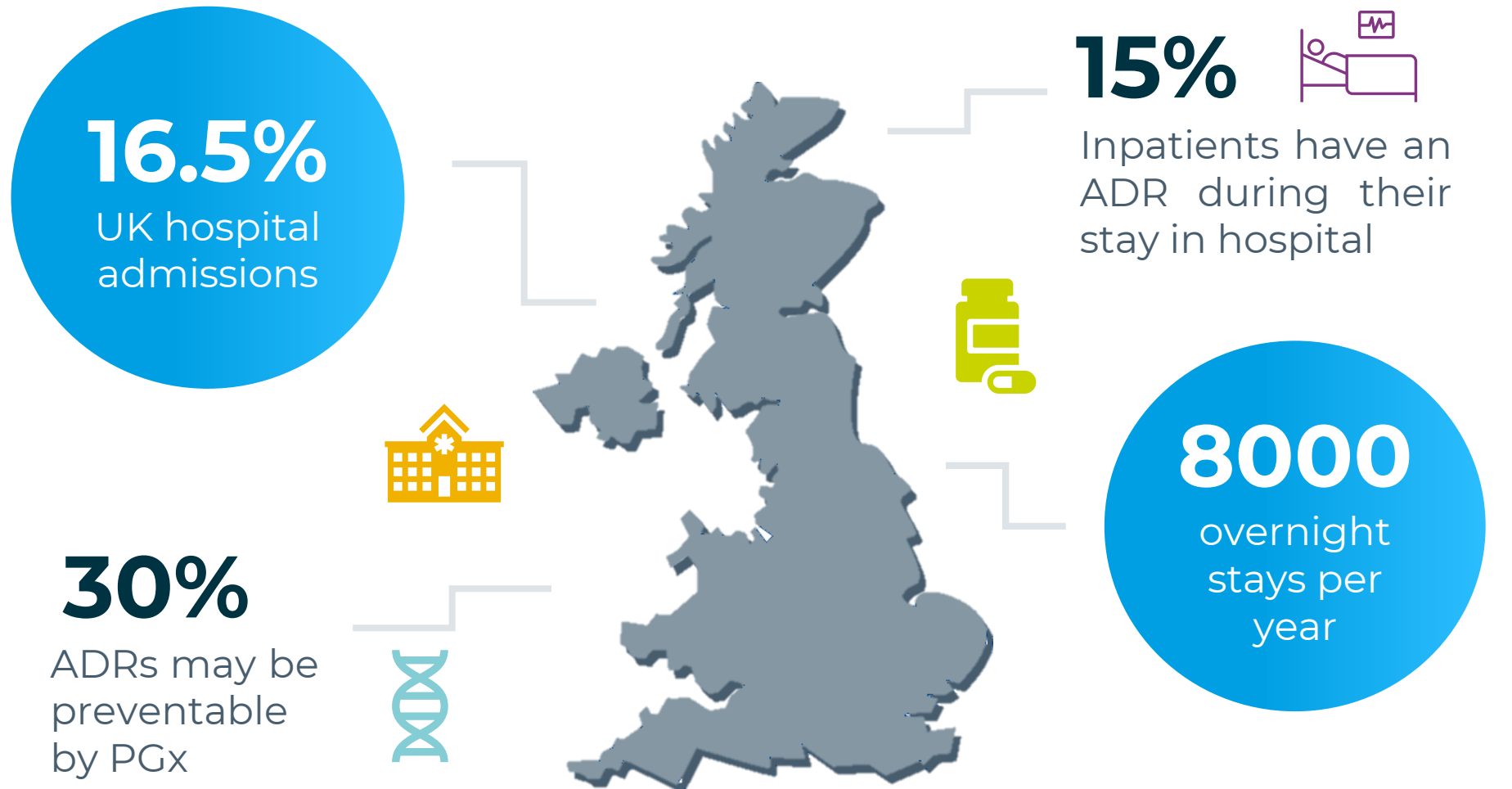
Genes can affect patient response to medication

Using pharmacogenetics can **improve patient safety** by quickly testing for genes known to cause ADRs

<https://medregs.blog.gov.uk/2023/10/02/the-role-of-genetics-in-medicine-safety/>

UK Health System – Impact of Adverse Drug Reactions

1. <https://medregs.blog.gov.uk/2023/10/02/the-role-of-genetics-in-medicine-safety/>
2. <https://bmjopen.bmj.com/content/12/7/e055551>



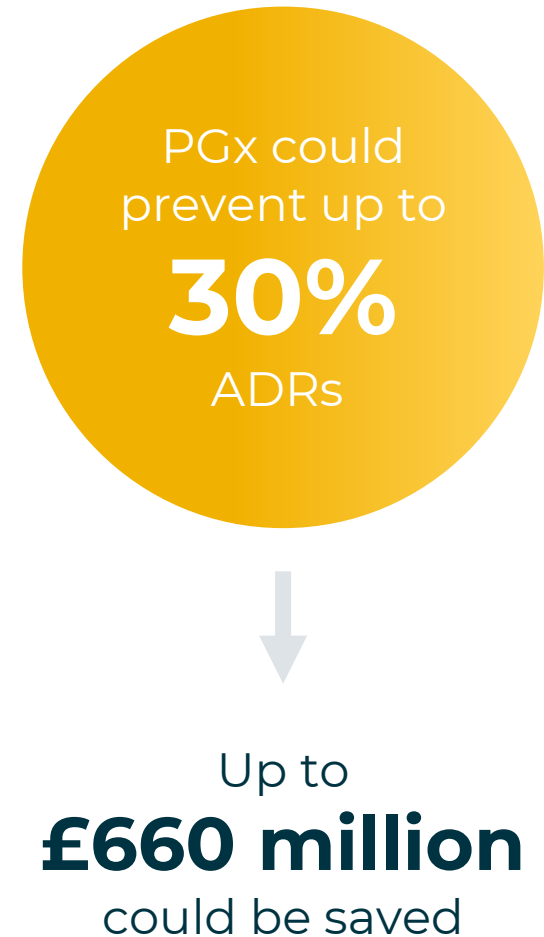
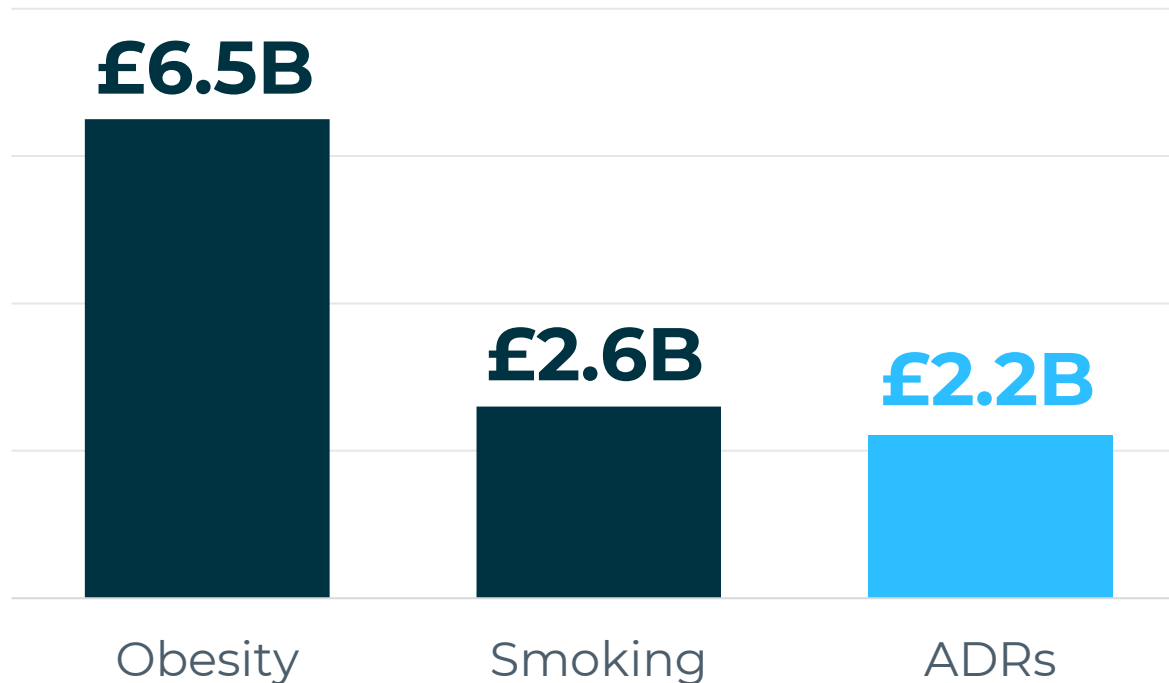
Adverse Drug Reactions: The Cost

<https://medregs.blog.gov.uk/2023/10/02/the-role-of-genetics-in-medicine-safety>

Obesity: [Government plans to tackle obesity in England - Department of Health and Social Care Media Centre \(blog.gov.uk\)](#)

Smoking: [NHS England » Guide for NHS trust tobacco dependence teams and NHS trust pharmacy teams](#)

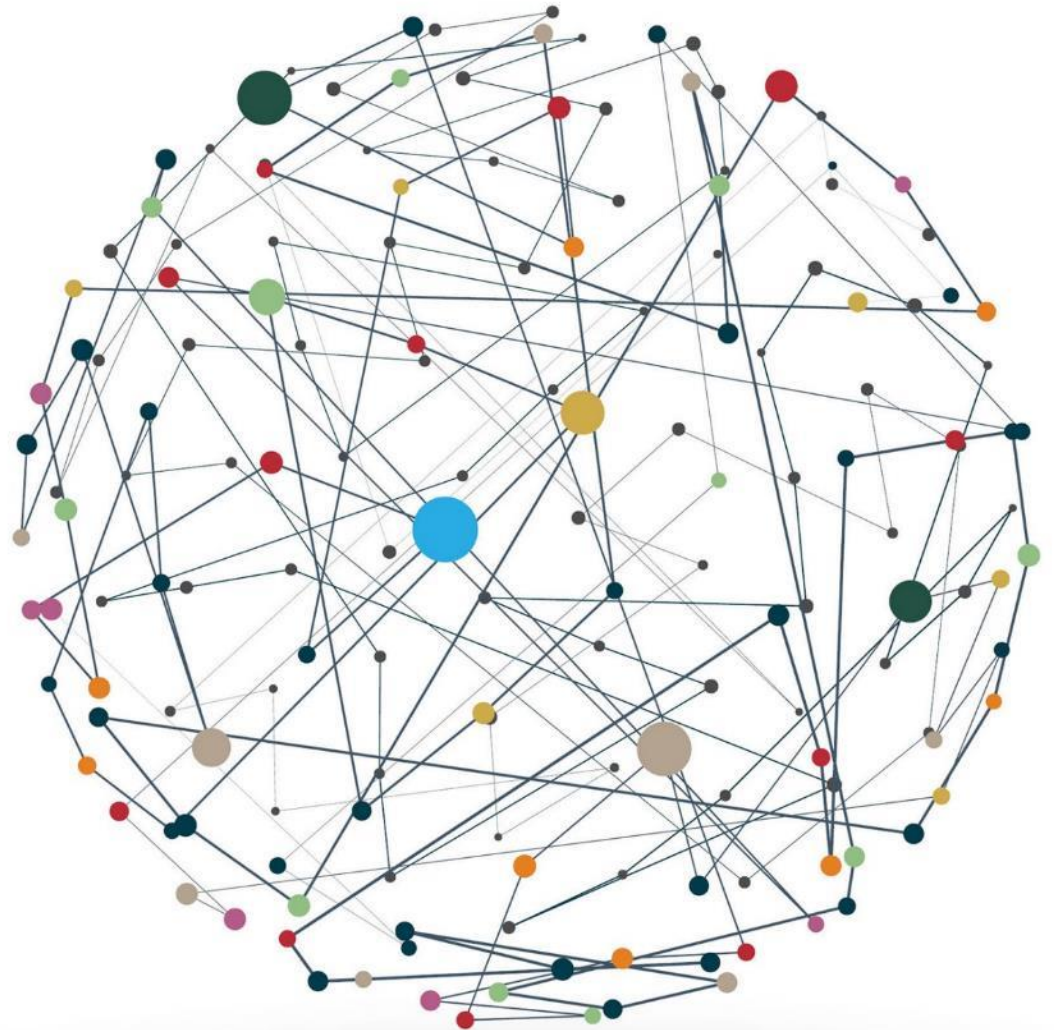
Annual Cost to NHS England





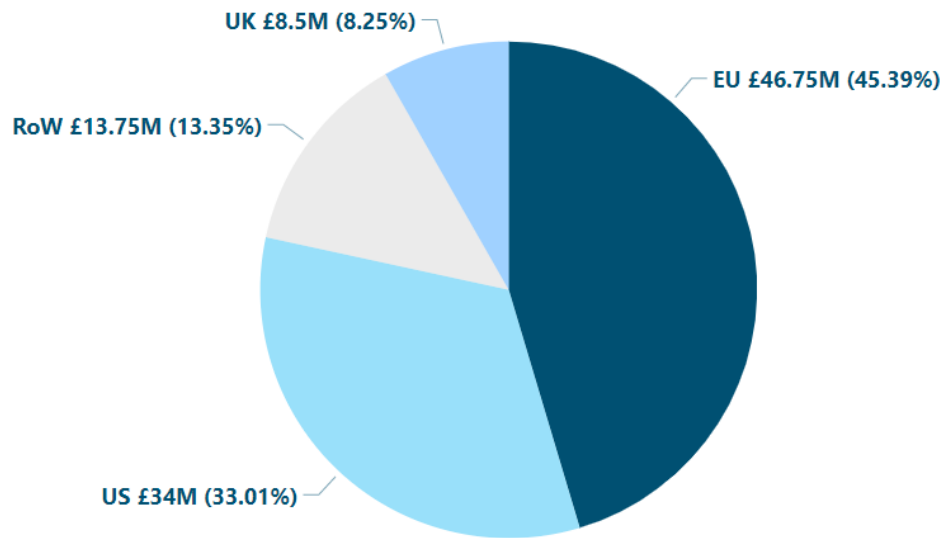
Genedrive® MT-RNR1 ID Kit

**Antibiotic Induced
Hearing Loss
(AIHL)**



AIHL - Antibiotic Induced Hearing Loss (Genedrive® MT-RNR1 ID Kit)

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 Marked

**Positive
Health Economic Case**

**NICE recommended for
use under EVA**

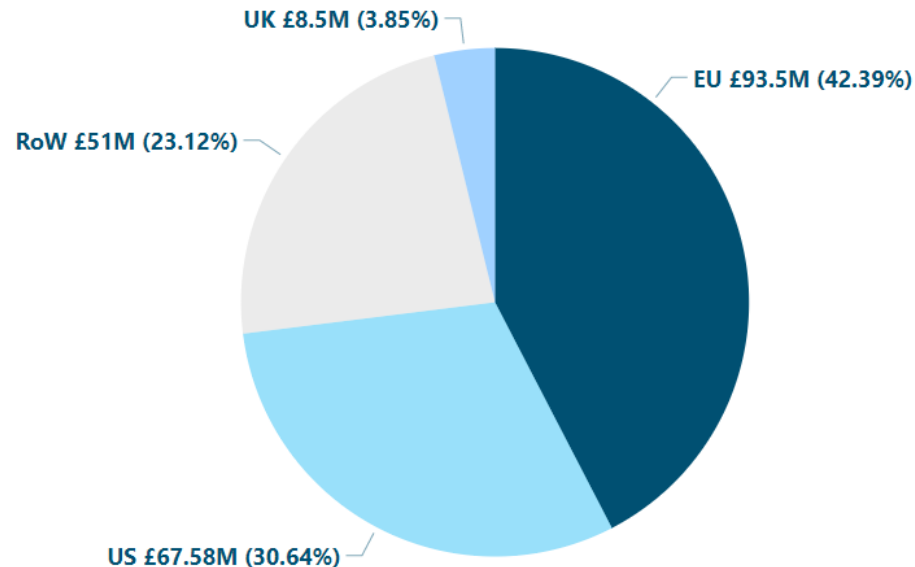
genedrive

Genedrive® CYP2C19-ID Kit



Genedrive® CYP2C19-ID Kit (in development)

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
- Uses end user pricing

**Addressable Market
for ischemic strokes.**

**~85K ischaemic strokes
per year UK**

**Up to 30,000 UK patients
could get better health
outcome**

**Co-operation with MRI
save >£1m in
ongoing costs**

Under NICE review

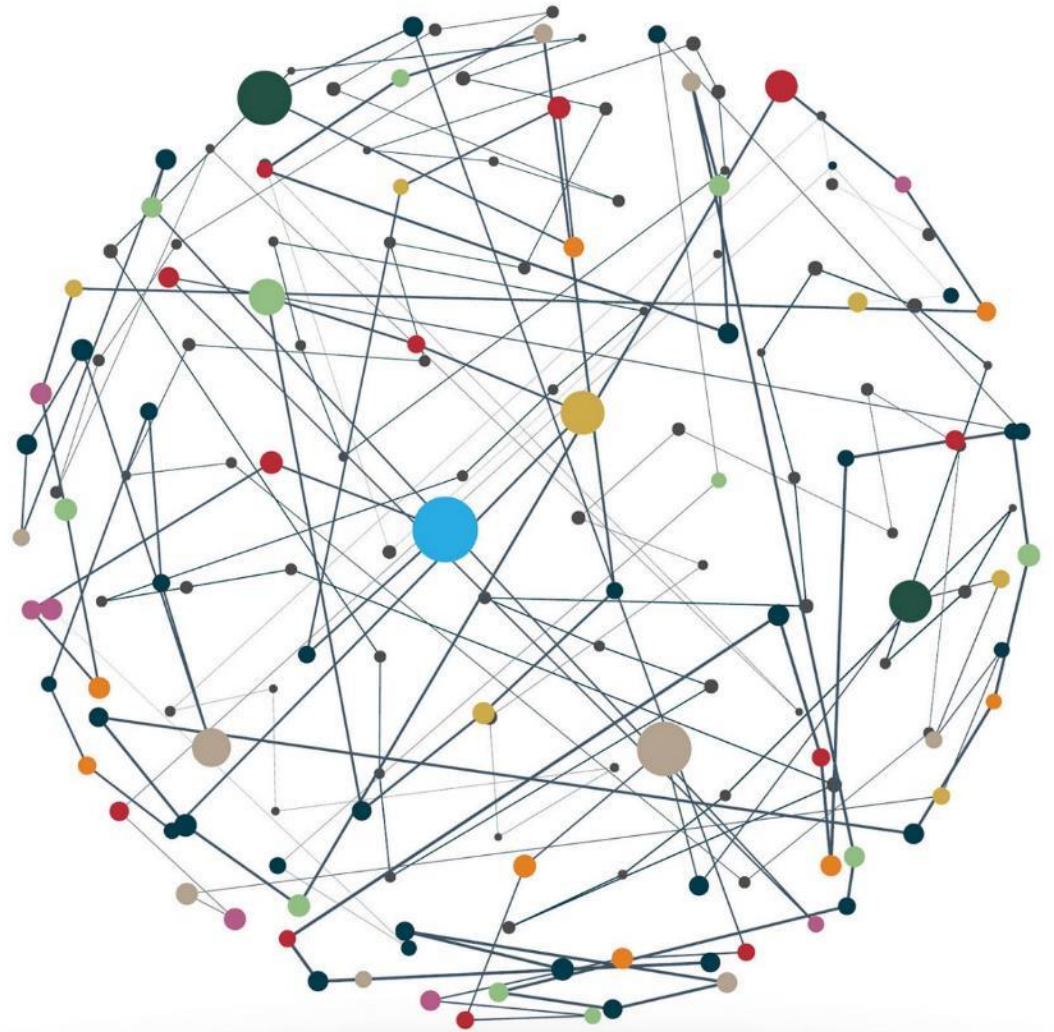
USA Clopidogrel ADR cost review 2023

American Journal of Health-System Pharmacy, Volume 80, Issue 12, 15 June 2023 – Veterans Health Administration

Unadjusted and Adjusted Comparisons of Mean Costs of Hospitalization for Different Drugs Associated With Same Adverse Reaction (at MedDRA HLT Level),
Summarized for Fiscal Years 2014-2018

		No. reports	Median (IQR) ^a	Mean (SD) ^a	Model estimate of cost, mean (lower and upper) ^b		
Clopidogrel		38	\$13,647 (\$9,547-\$18,581)	\$16,960 (\$13,401)	\$13,265 (\$8,650-\$20,342)		
^a Costs in US dollars adjusted to 2018 value using Consumer Price Index. Median and mean costs derived from raw data.							
^b Generalized linear model with gamma distribution and Bonferroni correction for multiple comparisons. Model adjusted for age, sex, race/ethnicity, presence of drug-drug interaction, and geographic region.							

Summary Financials



Summary Financials

Income statement	FY23 £'000	FY22 £'000
Revenue	55	49
R&D costs	(3,924)	(3,871)
Admin costs	(1,355)	(1,793)
Operating loss	(5,224)	(5,615)
Finance costs	(757)	(16)
Loss before tax	(5,981)	(5,631)
Tax	831	956
Loss after tax	(5,150)	(4,675)

Income statement

- Revenue - RNR1 in routine use
- R&D focused on near-commercialisation product development
- Admin costs reduced £0.4m due to tight cost management
- Finance costs includes £0.6m non-cash fair value adjustment
- R&D reflects reduction in HMRC R&D tax relief rates

Summary Financials

Cashflow

	FY23 £'000	FY22 £'000
Cashflow from operations	(4,874)	(5,327)
Working capital	231	(433)
Taxation	956	1,166
Other	(238)	(85)
Net cashflow from operations	(3,925)	(4,679)
Proceeds from investment funding	1,937	6,694
Net cash flow	(1,988)	2,015
Cash at bank b/f	4,589	2,574
Cash at bank c/f	2,601	4,589
Underlying monthly burn rate:	FY23 £'000	FY22 £'000
Gross	(407)	(487)
Adjusted for taxation	(327)	(390)

Cashflow

- Cash consumption from operations is £0.4m less than FY22 - reflective of the reduction in overheads
- Working capital inflow £0.2m – £0.7m higher than the £0.4m consumed in FY22 due to reduced stock expenditure
- £1.0m receipt from HMRC R&D tax credit scheme
- Other included £0.1m receipt disposal of discontinued operation in FY22
- Investor Placing Agreement net of costs
- Unaudited cash at 23 November 2023 of £1.0m

Burn rate

- Underlying cash consumption of £0.4m
- Adjusting for R&D tax credit received, monthly rate reduces to £0.33m

News flow

Near Term

- Revenue from additional go-live sites in the UK and abroad for MT RNR1
- Completion of the initial work with the Health Innovation Network for the MT RNR1
- Continue progressing special commissioning for MT RNR1
- Finalise position for FDA registration for MT RNR1
- Further NICE data gathering for full recommendation commences MT RNR1
- NICE review for CYP2C19
- Commence testing with MRI for CYP2C19
- Continuation of instrument design improvements to facilitate adoption, and expansion of test menu expansion
- Future funding activities to support FDA and product development

Medium to Long Term

- Commence IVDR registration for CYP2C19
- Launch of CYP2C19 in other territories following IVDR registration
- Commence FDA registration for MT RNR1
- Commence work on multi target pipeline tests

Summary

Great commercial traction for MT RNR1 both UK and abroad

Real clinical and commercial interest in CYP2C19 both in and outside the UK

First to market with unique Point of Care Pharmacogenetic testing

Investment required for growth capital to support sales strategy