

AI in healthcare: overview, examples, implications

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DYNAMIC AI:

Digital Innovation with Remote Management and Predictive Modelling to Integrate COPD Care with Artificial Intelligence-based Insights: An Acceptability, Feasibility and Safety Study

- Chronic Obstructive Pulmonary Disorder
- 120 000 people in Scotland
- Preventative, progressive
- Exacerbations
- Frequent hospital admissions





Introduction

- **Background and context**
- **DYNAMIC AI Overview**
- **Regulatory Framework**
- **Informed Consent**
- **Data privacy and Security**
- **Trial management**
- **Next steps**

**What do we mean when we
talk about 'AI' in healthcare?**



Technologies used to allow computers to perform tasks that would otherwise require human intelligence, such as visual perception, speech recognition, and language translation

Scotland's AI Strategy

Systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals

High-level Expert Group on AI, European Commission

The use of digital technology to create systems capable of performing tasks commonly thought to require human intelligence.

Office for Artificial Intelligence, UK Government





- Discussion around most accurate definitions
- Machines using statistics to recognise patterns in large amounts of data, including those not perceptible by humans
- Performs repetitive tasks with data, without the need for constant human guidance
- Mostly ‘machine learning’ – digital systems that improve their performance at a particular task over time, through experience
- Supplements rather than supplants



AI is often a **medical device**

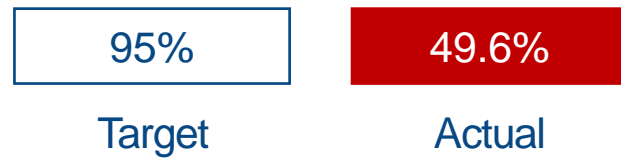
- If it's used to treat, diagnose, cure, mitigate, or prevent disease or other conditions – it's normally classified as a medical device
- Just like any other medical device, it needs to be regulated, calibrated, monitored, maintained and controlled

Why use AI?

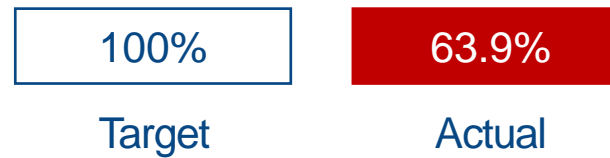


The system is overloaded

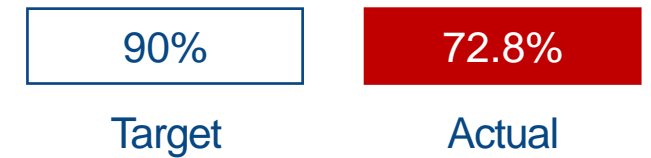
Outpatients should be seen <12 weeks after referral



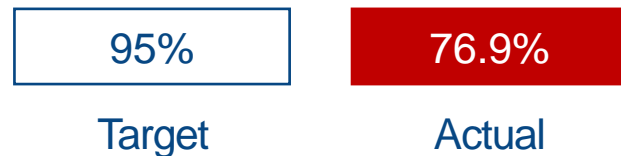
Wait <12 weeks from decision to treat, to treatment



Begin treatment within 18 weeks of referral



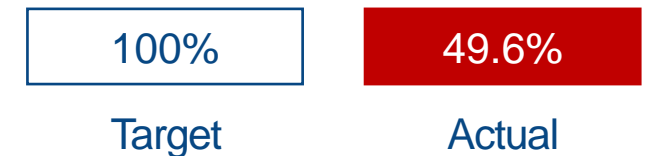
Wait <62 days from urgent suspicion of cancer referral to treatment



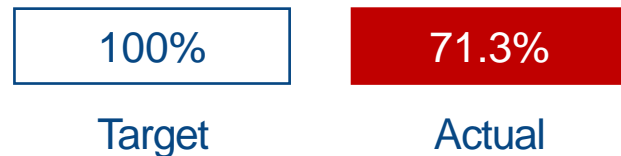
Wait <31 days from decision to treat cancer, to treatment



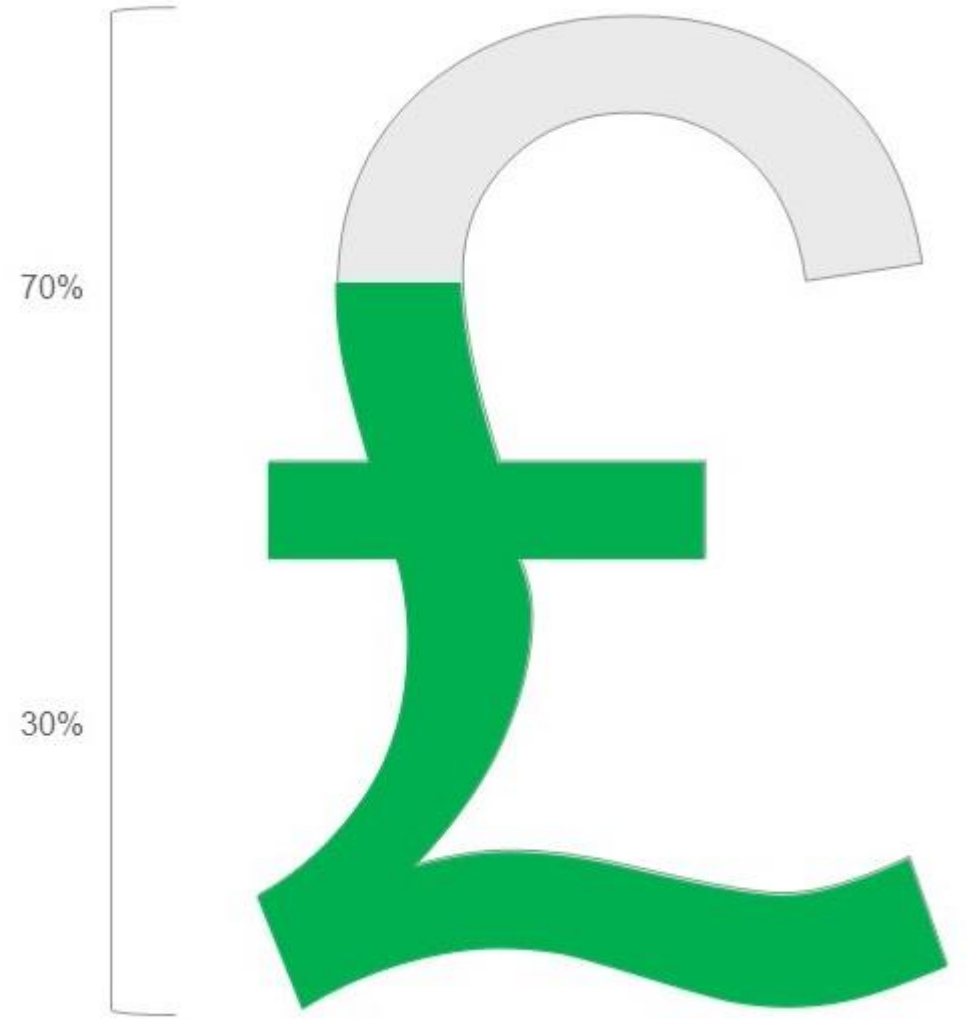
Wait <6 weeks for key diagnostic tests



ED admission, transfer or discharge within 4 hours of reception



Chronic conditions like COPD account for a disproportionate share of healthcare resources and are tied to inequalities



ROLE FOR INNOVATION



Targets are
being missed



Financial
constraints



Workforce
pressures



Demand is
increasing



Improved
outcomes

Demand will increase by a further
60% by 2040

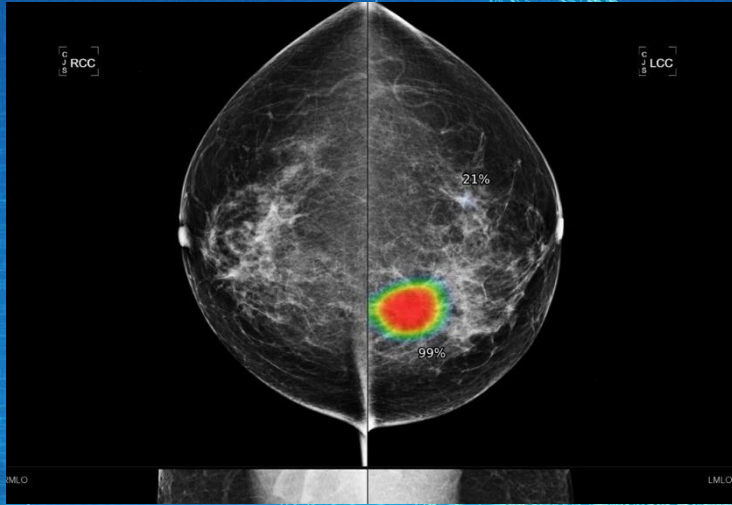
This demand **cannot** be met by
human resource alone

Where can AI be used?



Some examples

- Breast Cancer Screening (Imaging)
- Heart Failure Pathway
- Cancer Diagnosis (Pathology)



OPERA

Results from the Optimised Pathway for Early Identification of Heart Failure in the Community (OPERA) project - a collaboration between AstraZeneca UK, NHS Greater Glasgow & Clyde, University of Glasgow, Lenus Health and West of Scotland Innovation teams

2 weeks

Waiting time reduced from 12 months to 2 weeks for a population of 1.2 million

2 minutes

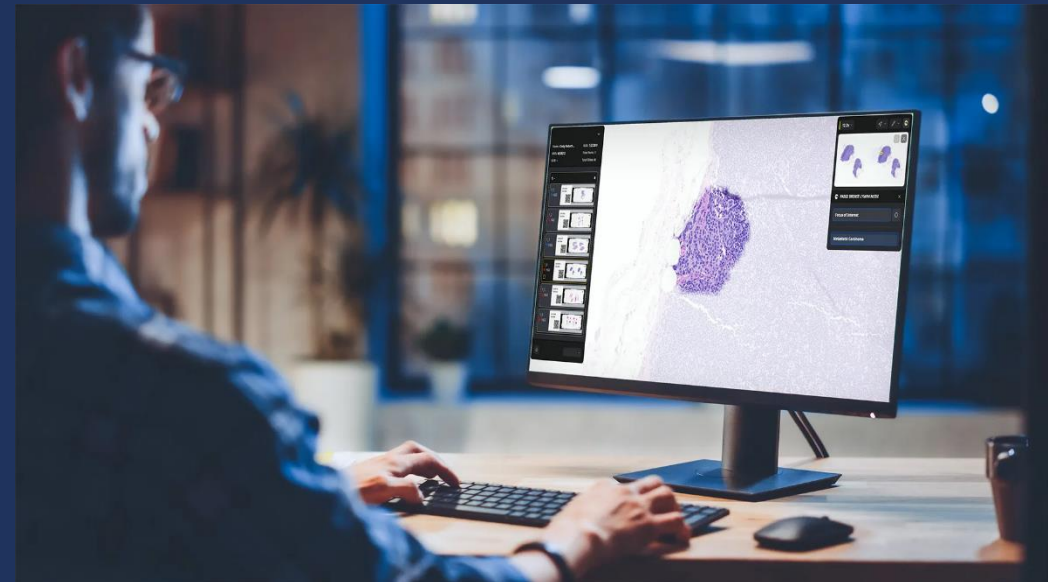
Echo analysis times reduced from 25 to 2 minutes by operationalising AI tools

30 %

Referrals diverted by enabling active clinical referral triage (ACRT)

150 %

Increase in diagnostic efficiency based on patients diagnosed in a 4hr clinic





Considerations for healthcare organisations





Challenges

Public awareness and concerns

Safety

How to realise benefits

Relevant regulations

Change management

Performance

Strategy and policy development

Transparency and explainability

DYNAMIC AI



COPD Digital Transformation

Patient App

Daily symptom diary and patient reported outcomes (PROs)

Asynchronous messaging direct to clinical team

Self-management information

Clinician Dashboard

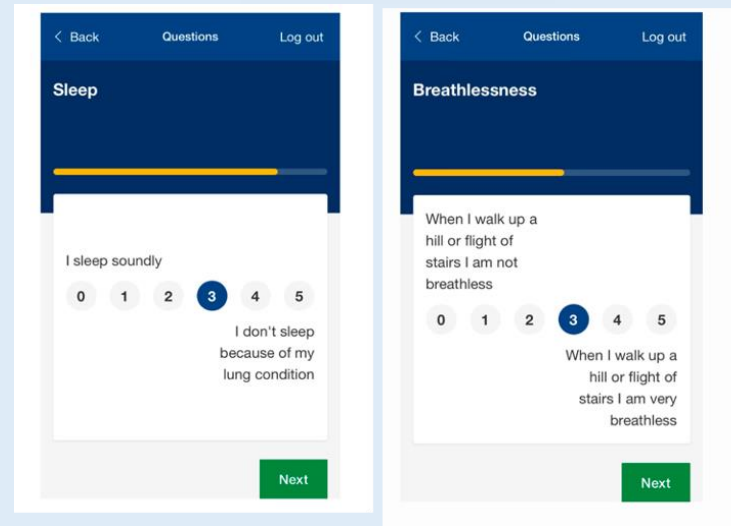
PRO and connected device data

Clinical data

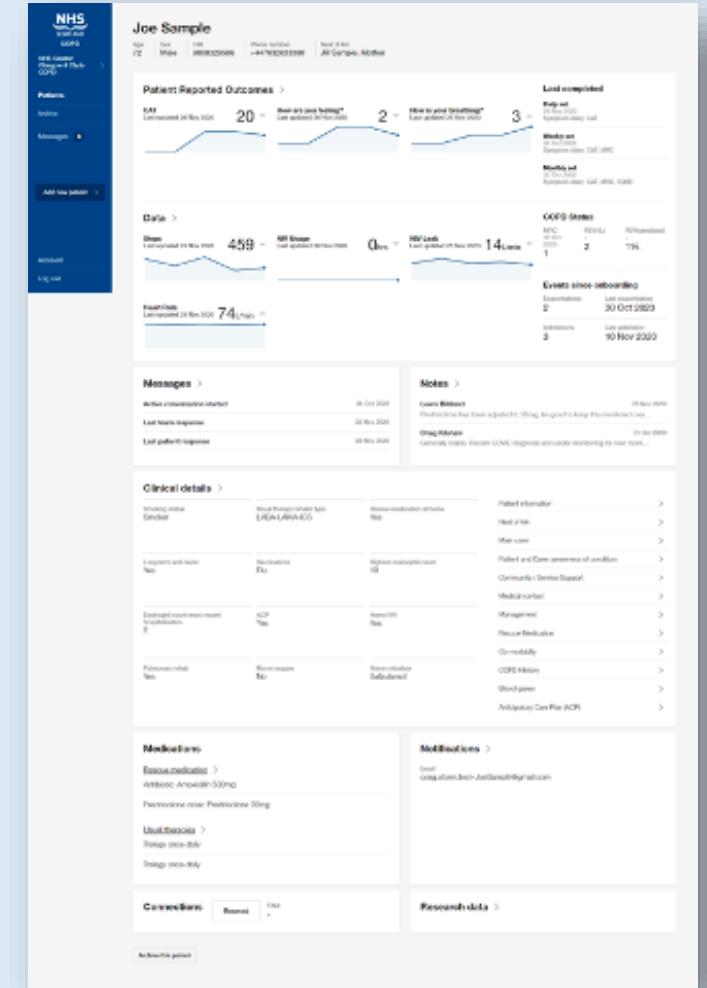
PDF export to electronic health records application



Patient web application – self management information



Patient web application – symptom diary questions

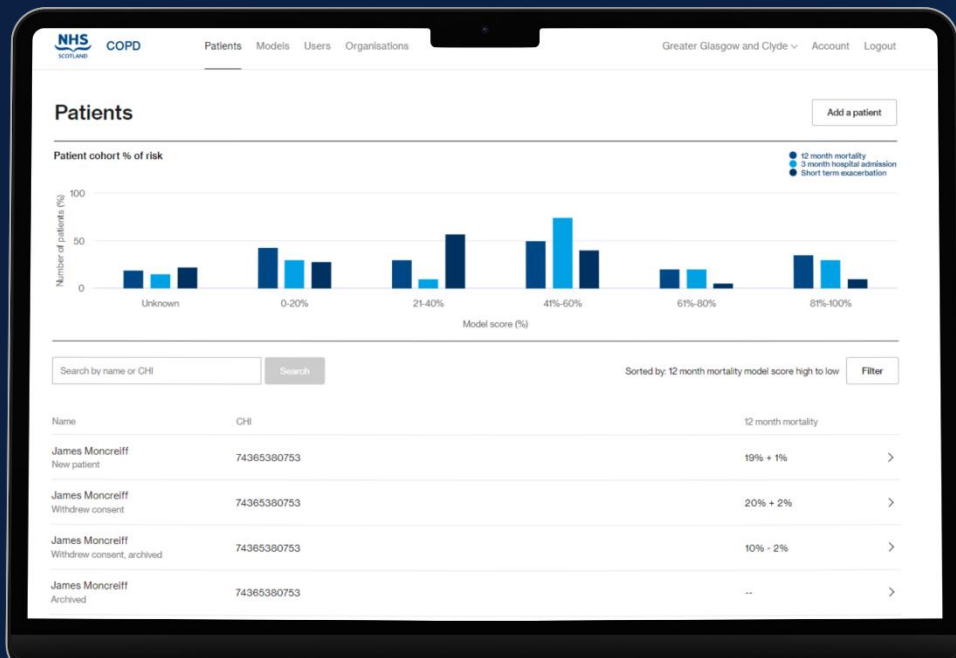


Clinician Dashboard – clinical information available during patient-clinician interaction

What is DYNAMIC AI?



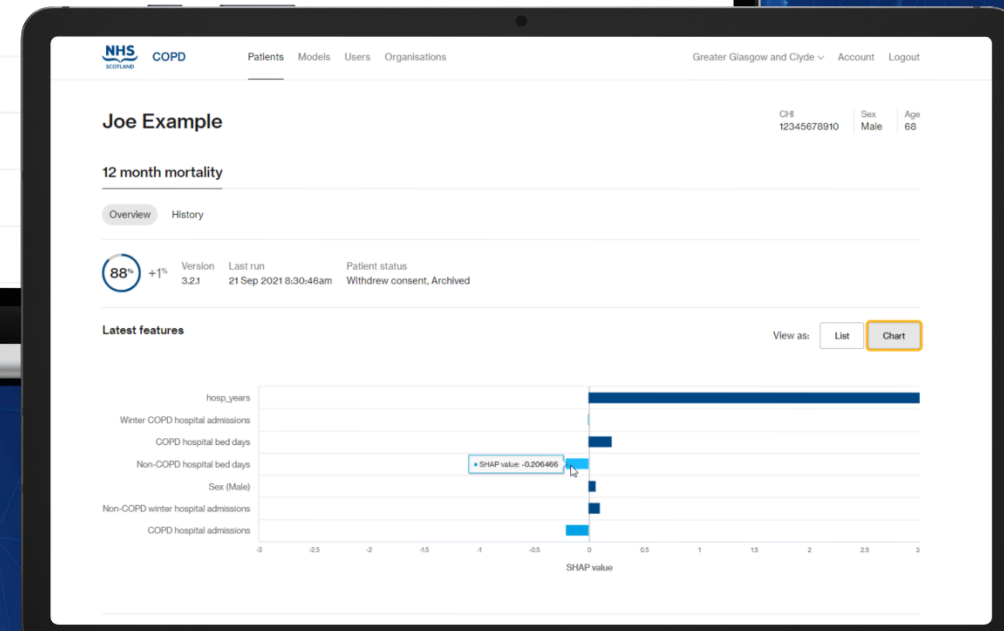
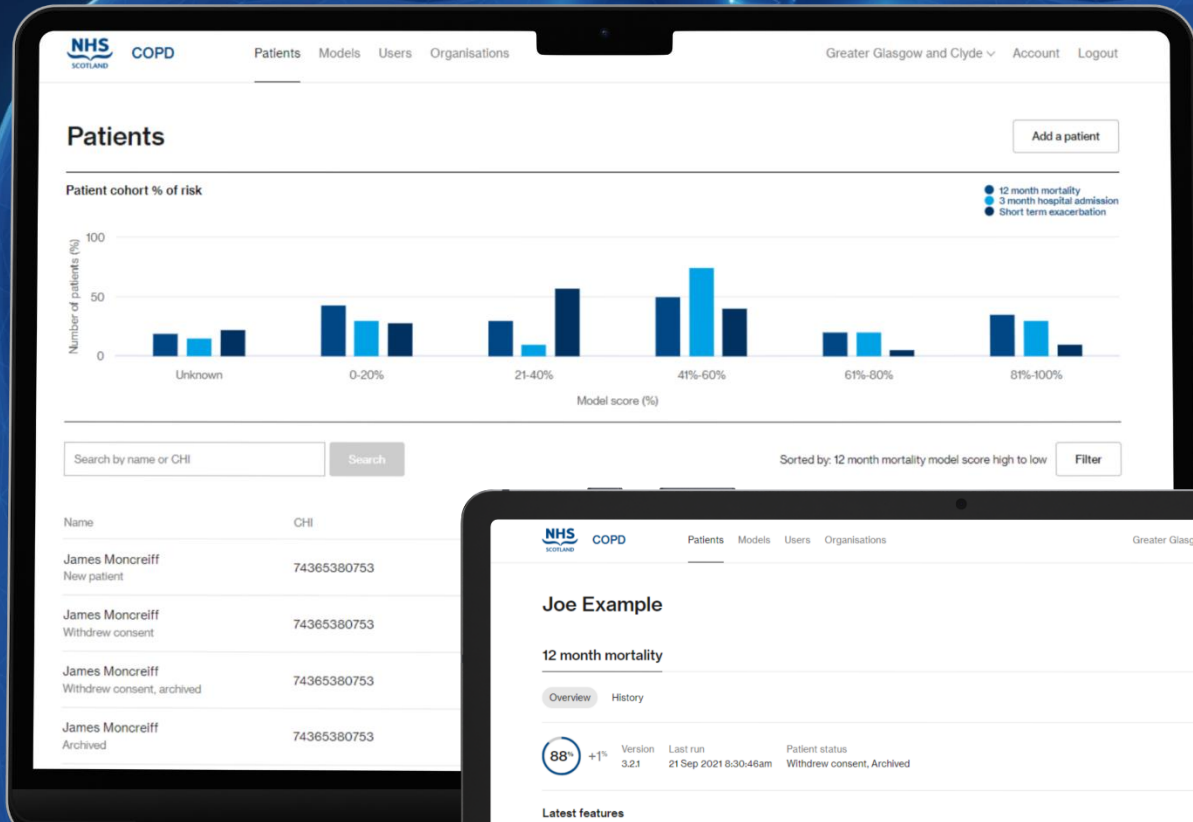
Medicines &
Healthcare products
Regulatory Agency



- MHRA Regulated Clinical Trial
- Medical Device (non- CE/CA mark)
- AI Insights Application
- Machine learning predictive models
 - 12 Month Mortality
 - 3 month re-admission
- Determine feasibility, acceptability and safety

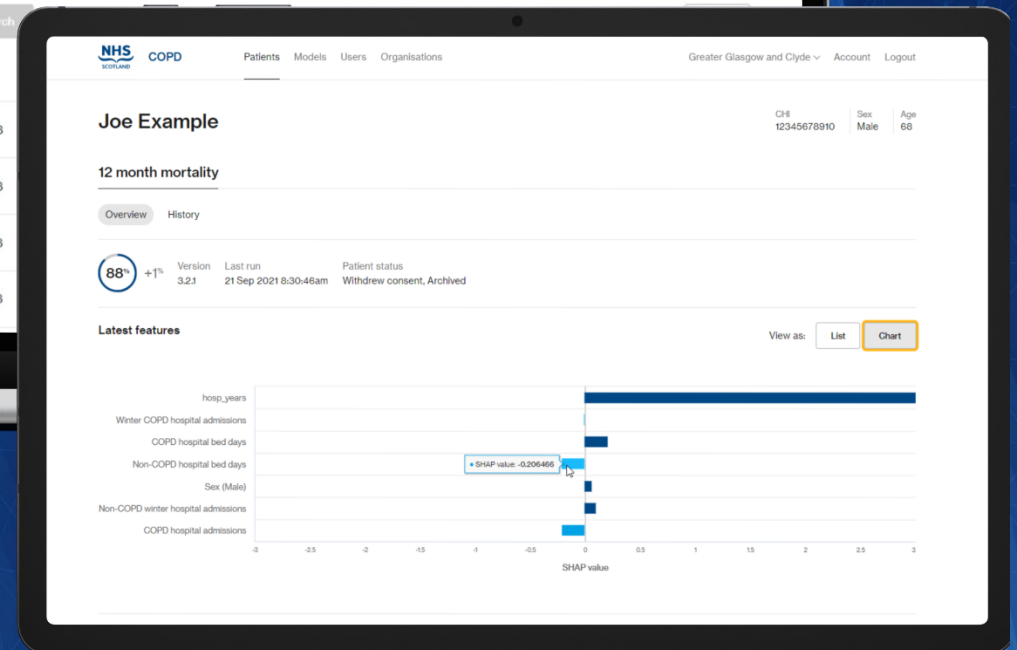
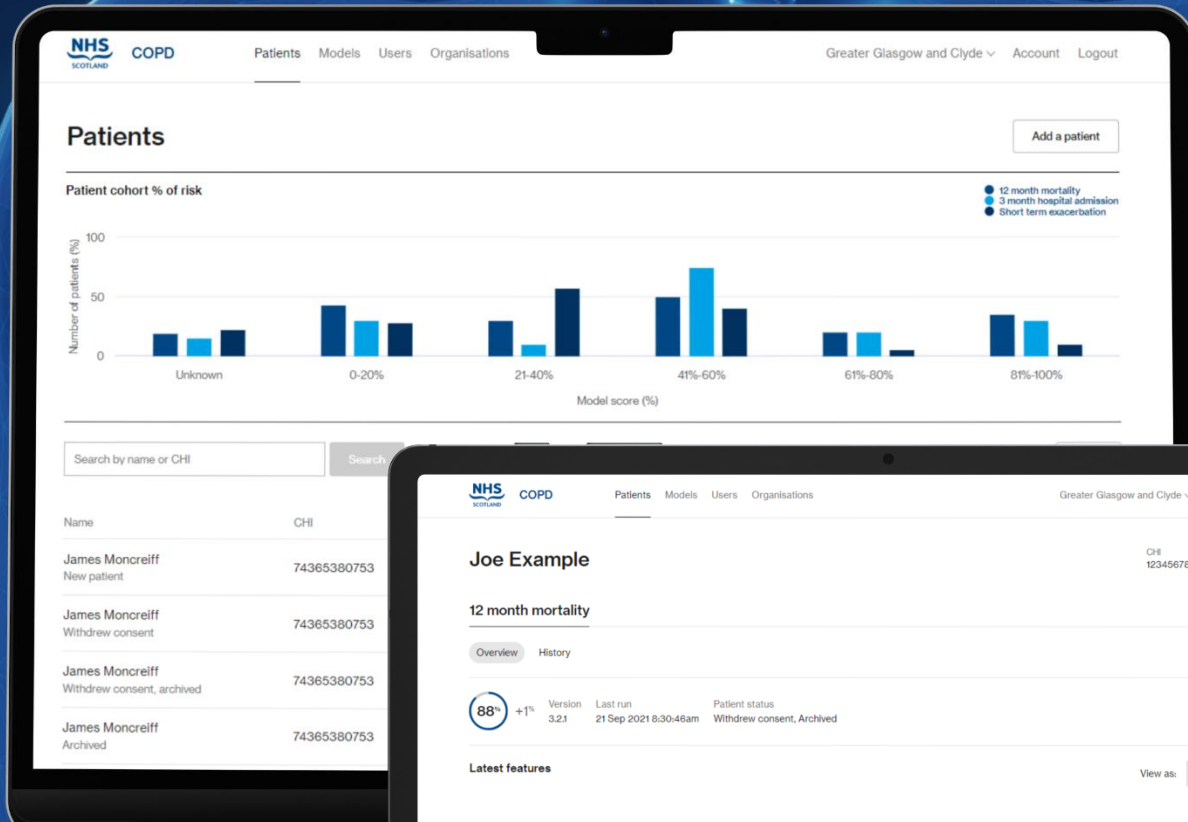
What is DYNAMIC AI?

- Risk based stratification
- Clinical MDT Discussion
- Actionable Insights
- Decision Support
- Informed direction of resource



Planning and set up

- MHRA Clinical Trial Application
- Ethical Approval
- Document preparation
- Research Protocol
- Investigators Brochure
- Patient-facing documentation
- Patient-Public Engagement



Regulatory Framework



➤ **MHRA Regulated Trial**

- Medical Device Regulations 2002
- Clinical Trial Application- 'Notice of No Objection'
 - Trial document set
 - Technical documentation

➤ **Experience**

- Clinical trials using AI are relatively new
- Feedback from MHRA during application process
- Dialogue between researchers and regulators ongoing



Informed Consent

Digital Consent Process

Requirement of Good Clinical Practice

AI brings additional responsibility to explain clearly

< Back COPD Log out

COPD DYNAMIC-AI study
Consent

Before you join the study, we need your permission to access and use your information. By providing your permission, you will automatically join the study.

If you choose to give us your permission, we will confirm you've joined the study and send you a copy of this information by email.

Reading confirmation

I confirm that:

- I have read and understand the information sheet dated <<Current Date>> version 1.0 for the above study
- Date>> version 1.0 for the above study and have had the opportunity to ask questions which have been answered fully
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- I understand that information I provide as part of the study and information from my medical records may be accessed by responsible individuals from NHS Greater Glasgow and Clyde, the Robertson Centre for Biostatistics at the University of Glasgow, Lenus Health Ltd, Storm ID, and regulatory bodies where it is relevant to my taking part in this research. I give permission for these individuals to access my provided information and records that are relevant to this research.
- I agree to take part in the above study.

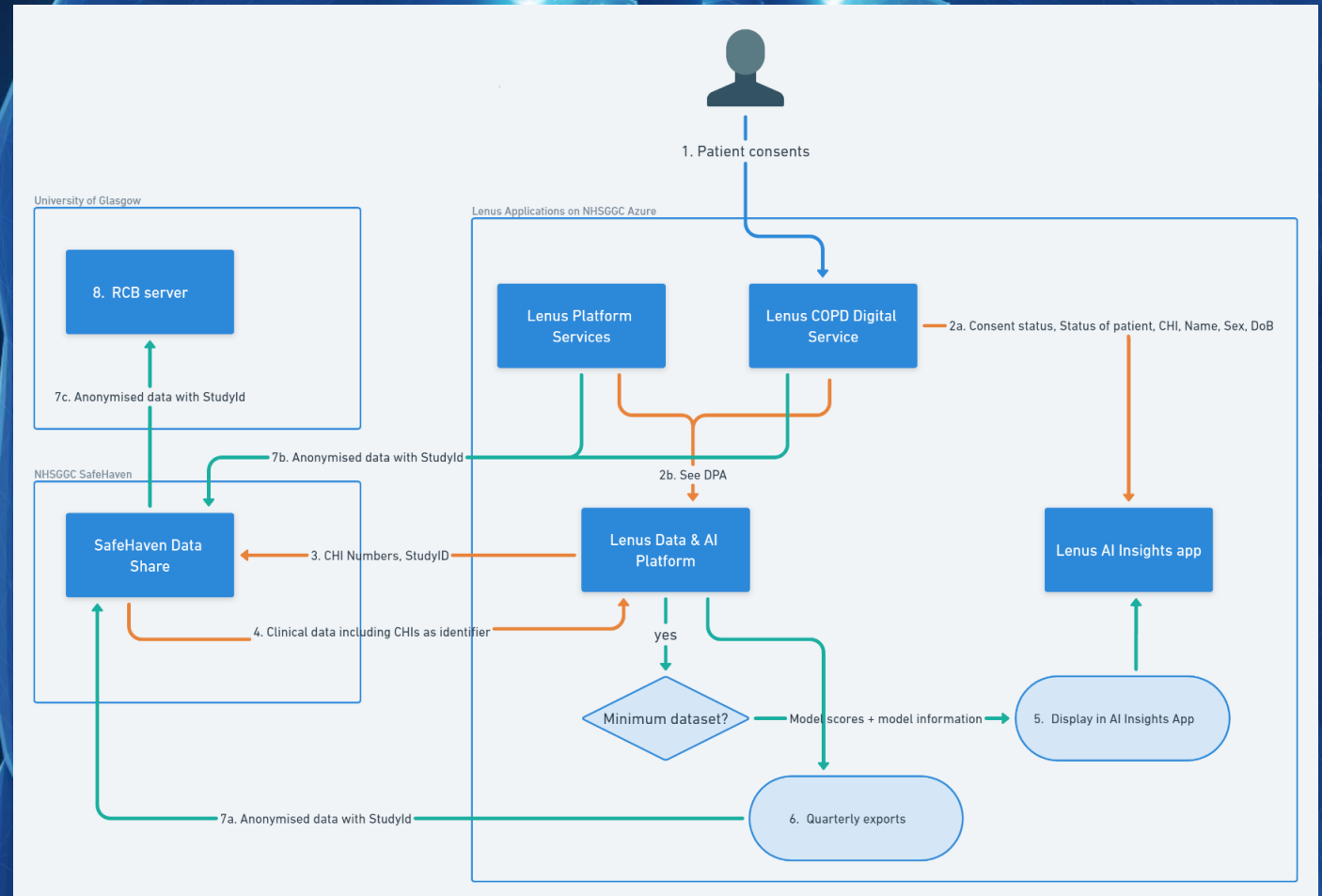
Yes
 No

Data Privacy and security



How data is used in DYNAMIC AI

- Model training
- Model Inferencing
- Research datasets
- Production data from Lenus COPD (Digital Service)



Data Protection Regulations



- AI falls under existing regulations
- UK GDPR and Data Protection Act
- Health board is data controller
- Internal Information Governance
- Data Protection Impact Assessment
- Data Processing Agreements for data processing and transfers
- Next steps

Trial management



Trial Management



- **Sponsor Governance**

- Compliance, Safety reporting, monitoring

- **Trial Management Group**

- Independent Oversight

- Executive function

- **Model Approval Process**

What next for AI in healthcare?





Challenges

Public awareness and concerns

Safety

How to realise benefits

Relevant regulations

Change management

Performance

Strategy and policy development

Transparency and explainability

Making the transition

Innovation

Service Evaluation

Evidence

Trust

Change Management

Post-Implementation
Surveillance