House Rules

Welcome!

- **Transparency**: Anyone is free to use information from our discussion, particular comments will not be attributed to individuals

- **Optimism**: Providing contributions that are positive and solutions-focused

- **Respect**: Promoting a culture of tolerance and inclusivity

- **Courage**: Be prepared to try new things and challenge

- **Humility**: Learning and respecting others and their diverse views

To read our meeting guidelines and etiquette in full visit our website:

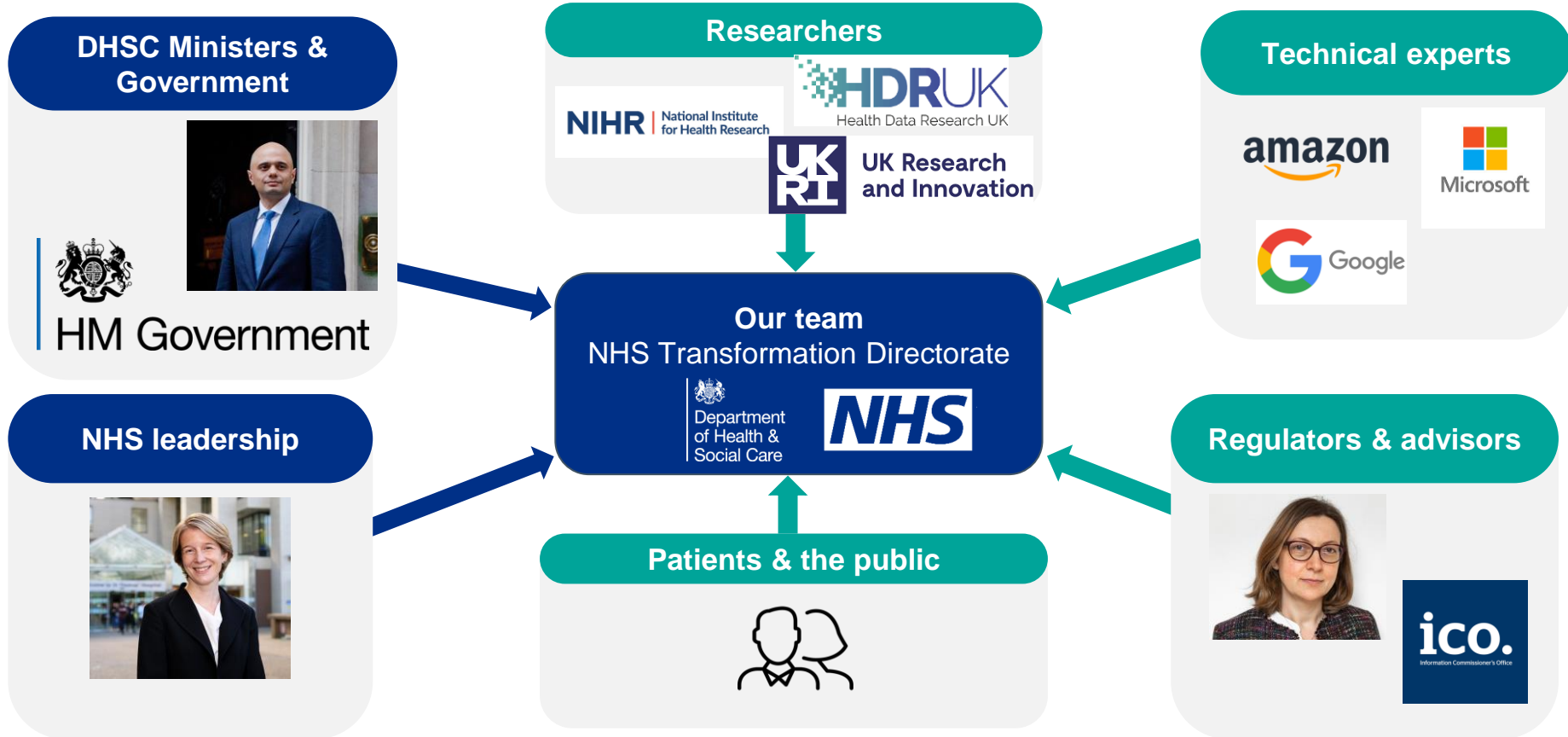www.hdruk.ac.uk/news-opinion-events/events/

Secure Data Environments

21st April 2022

Who we are

NHS data for analysis and research

Opportunities

Better evaluation to improve quality, cost and safety of care

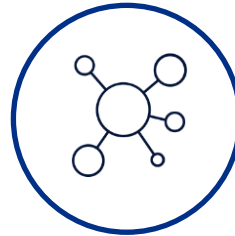**Better understanding of treatments and side effects**

Better development of new therapies and diagnostics

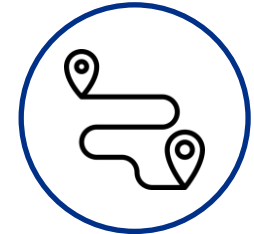**Better basic research into disease and cause**

Barriers

Fragmented system which is hard to navigate

Reliant on user compliance and pseudonymisation

Major projects have lowered public buy-in

Slow moving and cautious system for data users

The story so far

Critical data use in pandemic
2020-2021

Goldacre review commissioned
February 2021

Draft data strategy published
June 2021

Policy paper
Data saves lives: reshaping health and social care with data (draft)
Updated 10 February 2022

Clear direction of travel
Dec 2021

NHS England | Department of Health & Social Care

Principles and Best Practices for Trusted Research Environments

8 December 2021 ☘ Simon Madden (Director of Data Policy, NHSX), Catherine Pollard (Director of Tech Policy, NHSX)

Four criteria for GPDPR
July 2021

- The ability to delete data if patients choose to opt-out;
- The backlog of opt-outs has been fully cleared;
- **A Trusted Research Environment has been developed and implemented;**
- A campaign of engagement and communication.

GP Data for Planning & Research
June/July 2021

NHS data grab on hold as millions opt out

A plan to share GP data was set to launch in September, but an online summer campaign has prompted widespread dissent

Where are we now?

Up to **£200 million to boost NHS healthcare data research**
March 2022

Investment to be used for;
- A system of national and regional Trusted Research Environments
- Boosting data-driven clinical trials

UP TO £260M FOR NHS-LED HEALTHCARE RESEARCH AND TO EXPAND LIFE SCIENCES MANUFACTURING IN THE UK

A review commissioned by the Secretary of State for Health and Social Care

Better, Broader, Safer: Using Health Data for Research and Analysis

April 2022

Goldacre review published
April 2022

The review recommends to;
- Adopt data access platforms as standard across the NHS
- Transform career paths and leadership for NHS analysts
- Commit to open working practises to increase transparency
- Earn public trust through concrete action

Where are we going?

We envisage a future **data access ecosystem** made up of a limited number of Secure Data Environments. All organisations that provide access to NHS data will need to conform to national standards and be accredited.

Why are we shifting from data sharing to data access?

Public confidence

Data access provides much better security and enables increased transparency of how data is used.

NHS and DHSC

Enables better use of data to support population health management **decisions,** resource **planning**, and monitoring deployment of new **innovations.**

Researchers

Datasets can be securely linked with results, shared in a non identifiable way.

What are Secure Data Environments?

Secure Data Environments are digital platforms where sensitive NHS data can be **accessed** securely and entry is **tightly controlled**. Only analysts, researchers and innovators who meet specified requirements will be allowed access to Secure Data Environments.This is a significant improvement to current systems that rely on data **sharing**.

The benefits of Secure Data Environments

The features of Secure Data Environments make them critical to gaining and maintaining public trust:

- **Security:** Data does not need to leave the data controllers' systems. Only users and organisations that meet requirements are allowed access to the data.
- **Data value:** Allow for data sources to be linked at scale, and provide tools for analysing linked data in a standardised way.
- **Transparency:** Ability to record and audit all activity for oversight, and sharing analyses for interrogation and reuse by other users.
- **Privacy:** Only data that has been agreed as necessary for a project is made available to analyse and only summarised results can be exported via an airlock system.

A complex landscape of data use

Department of Health & Social Care

NHS

National

NHS Digital

OpenSAFELY

The NHS COVID-19 Data Store: putting data at the centre of decision making

In a crisis, knowledge is power - and a lack of it can cost lives. Different parts of the NHS were already capturing much of the data we needed to inform our COVID-19 response. However, without a single place to gather and analyse this data, decision-makers were unable to see a complete picture of the situation or move as quickly as the response to the pandemic demanded.

Regional

This year, awarded seed-funding to **plan and develop Trusted Research Environment capabilities:**
- Thames Valley
- London
- Wessex
- Greater Manchester

Department of Health & Social Care

Department for Business, Energy & Industrial Strategy

HDRUK
Health Data Research UK

NHS DigiTrials
Provided access and linked data for the RECOVERY Trial, saving thousands of lives.

PIONEER
Analysis of real-time data discovered an increase in venous thromboembolic events (VTE); developed guidance which is now being used in over 60 countries.

DATA-CAN
Estimated excess cancer patient deaths.

Discover-NOW
Supported a range of projects across London.

Gut Reaction
Enabled 34,000 people with inflammatory bowel disease to assess their risk.

BREATHE
Provided policymakers maps and hotspot data from 4.4.m people using the ZOE/ Kings College London Symptom Study.

BHF Data Science Centre
Enabled safe, secure access to health data for over 55 million people in the UK, to investigate the impact of COVID-19 on cardiovascular disease.

INSIGHT
Supported real world data analysis to identify impact on hospital eye services.

Cohort

Genomics england

biobank uk

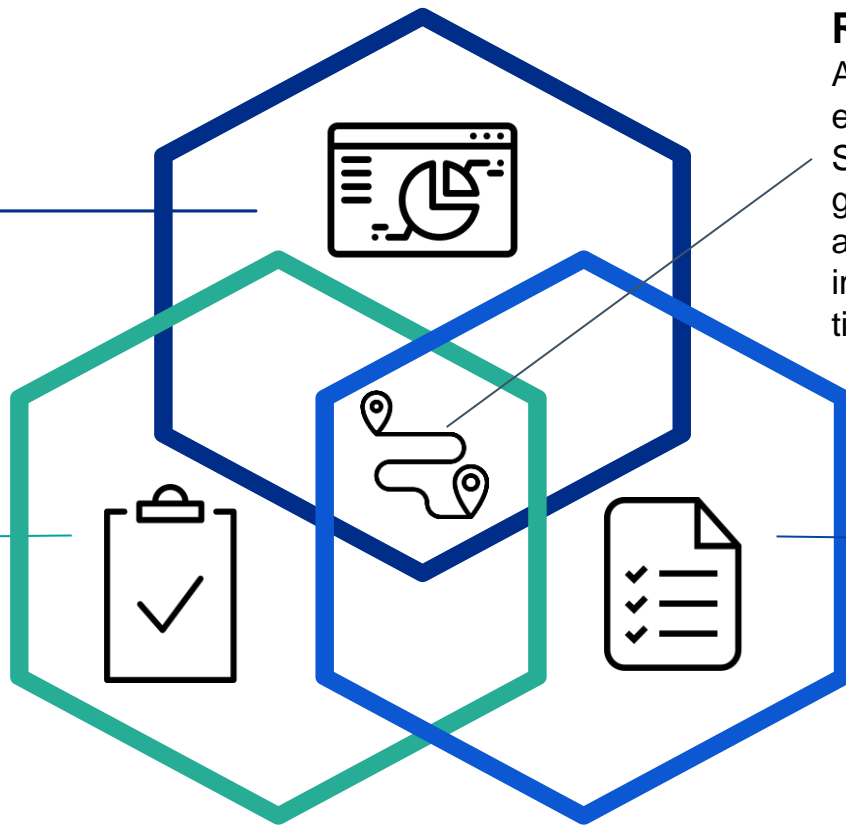**NIHR** | National Institute for Health Research

Our intended products

Policy principles
10 high level guidelines that will guide our approach to SDEs. To be published in Data Strategy

Technical capabilities specification
Defines technical capabilities required of SDEs, including security, functionality, access and data management.

Roadmap
A guidance document that explains the transition to SDEs. How the SDE guidelines, tech spec and accreditation should be implemented and over what timeline.

Accreditation framework
Details the specifications and standards that SDEs must adhere to, and how adherence will be assessed and monitored.
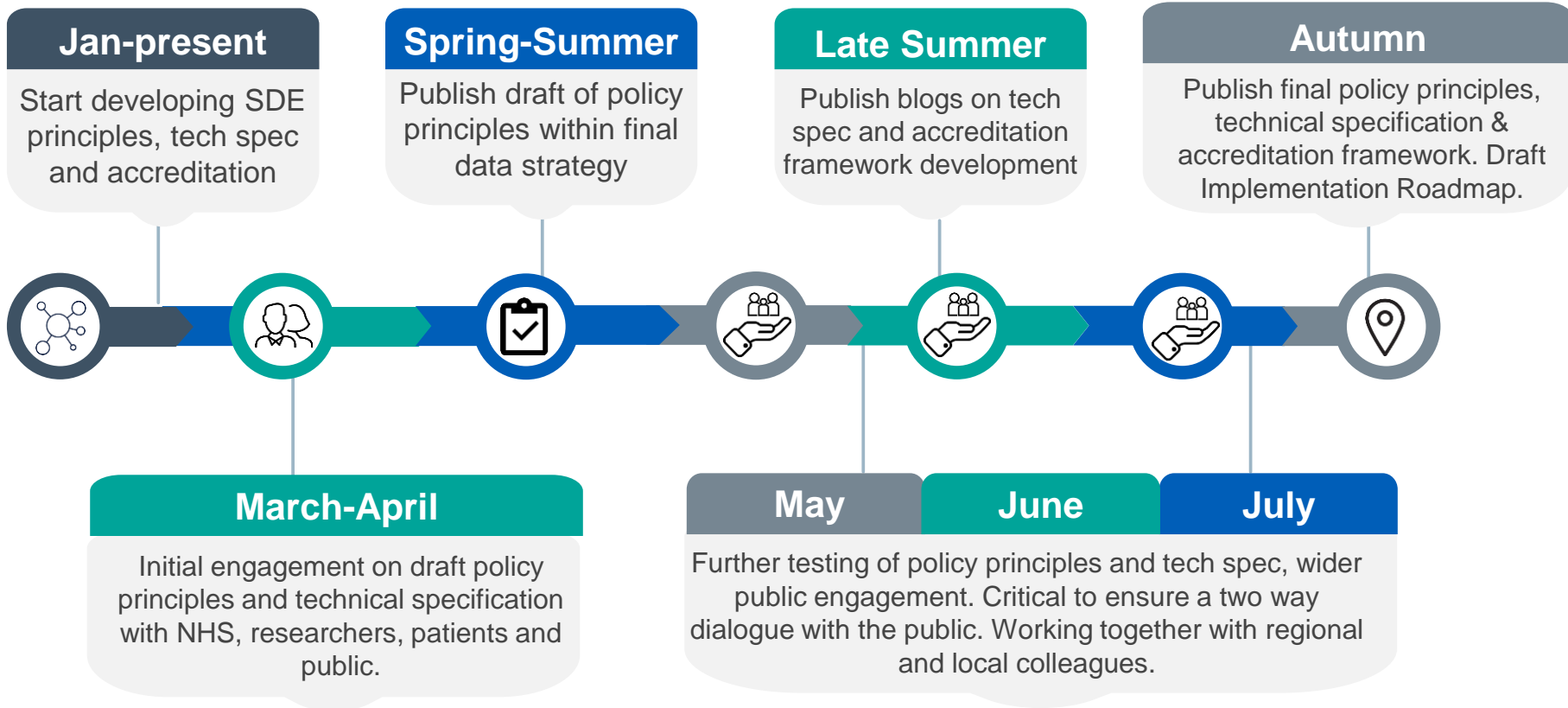
Our policy development

The direction we have set

- Secure Data Environments will be the default way that NHS data will be accessed and analysed, data sharing will be a highly limited exception.
- Our principles will be based on the "5 safes framework" developed by ONS
- Secure Data Environments that hold NHS data will need to be accredited on an agreed basis.
- Researchers/analysts and their host organisation will need to be accredited in order to use a Secure Data Environment.
- We will co-design our policy through public and patient engagement.

Areas where input will be needed

- How we achieve both tight controls to protect patient data while facilitating medical research and innovation in the NHS.
- How Secure Data Environment hosts will engage patients and the public in their governance mechanisms and decision making.
- The extent to which we should implement open data practices, e.g. publishing of code, disclosure levels of data use.
- Where there are justifiable exemptions to data access as default through a Secure Data Environments (e.g. consented clinical trials).

Our timeline

NHS

Jan-present
Start developing SDE principles, tech spec and accreditation

Spring-Summer
Publish draft of policy principles within final data strategy

Late Summer
Publish blogs on tech spec and accreditation framework development

Autumn
Publish final policy principles, technical specification & accreditation framework. Draft Implementation Roadmap.

March-April
Initial engagement on draft policy principles and technical specification with NHS, researchers, patients and public.

May **June** **July**
Further testing of policy principles and tech spec, wider public engagement. Critical to ensure a two way dialogue with the public. Working together with regional and local colleagues.

Upcoming HDR UK events

- HDR UK's next **Data Access and Discovery event** will be taking place on Thursday 9th June and will be run by our training team.

- The HDR UK **Bimonthly Science Webinar**, on mental health data, will be taking place on Tuesday 10th May.

Please visit **hdruk.ac.uk/events** to find out more and register.