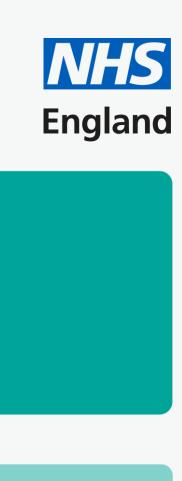
OpenSAFELY Data Analytics Service Pilot Directions 2025

Supporting information for Local Medical Committees





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Context and Pack Purpose

The pandemic OpenSAFELY COVID-19 service enabled researchers to <u>publish numerous COVID-19 related</u> <u>studies</u> using GP data linked to other health care data. Studies included factors associated with the risk of death from COVID-19, vaccination effectiveness and safety, and the effectiveness of COVID-19 treatments.

The OpenSAFELY technology is a secure trusted research environment with the following privacy protections:

- i) Each GP practice only shares coded patient data (no free text, documents or images); the practice remains data controller of this source patient data; all patient data remains inside the secure environment of TPP and Optum; only anonymous aggregate data is released for publication (following review by trained output-checkers);
- ii) Approved users (researchers, analysts, and data scientists) only see the aggregated outputs of studies;
- iii) All actions and study code run against the patient data is made transparent, logged in public, in real-time.

Supported by the GP profession, including privacy campaigners, NHS England committed to expand the OpenSAFELY service to allow GP data to be used for studies no longer restricted to COVID-19 purposes.

The NHS OpenSAFELY Data Analytics Service Pilot Directions 2025 was issued by the Secretary of State for Health and Social Care in June 2025. This confers a legal obligation on NHS England to issue a Data Provision Notice (DPN) requiring GP practices to make GP data (only coded data) available for studies beyond COVID-19. NHS England only becomes data controller of the intermediate GP data tailored to each study.

This pack is to support LMCs field initial queries, and if necessary to signpost practices back to NHS England.

Directions progress







Collaborative Communications

Collaboration to prepare for Directions release.

(stakeholders included BMA, RCGP, NHS England, DH, National Data Guardian, Citizens Juries, medConfidential)



Issuance

DHSC issues the Direction to NHS England on 9th June 2025.

(Comes into effect the day after signature)

July 2025

2nd Letter sent to GP practice to assist them with complying with the DPN.

The DPN is planned to be issued in late July.



FOR ACTION: This DPN applies to TPP (SystmOne) and Optum (EmisWeb) practices only. (Medicus practices are out of scope)

- Practices have 6-weeks to review and accept the DPN (i.e. by 2nd Sept)
- Practices confirm acceptance of the DPN by clicking a button on their GP system.

OpenSAFELY Data Analytics Service Pilot Direction Purposes

- Studies are no longer restricted to COVID-19 purposes. For each study submitted to access the Service:
 - NHS England must consult with the BMA and RCGP for advice.
 - NHS England must consult with the NHS England Advisory Group for Data.
- Two new types of studies are included:

Types of study permitted

Clinical audit

Service evaluation

Health surveillance

Research

NEW - Health & social care policy, planning and commissioning and public health purposes These studies **must** have the support of nominated representative of the BMA and RCGP

NEW - Evaluation of the Service (e.g. user experience; feasibility testing for new features.)

Opt-outs: National Data Opt-out & Type 1 Opt-out

National Data Opt-out

- As per existing NHS England policy, the National Data Opt-out for research and planning was initially not being applied for research and planning studies.
- Following discussions with the GP profession and medConfidential, NHS England has included
 an amendment to allow users of the service to make a request to apply the opt-out to their
 study (this would mean that on a study specific basis, patients who have registered a national
 data opt-out would not have their data included in a research or planning study).

Type 1 Opt-out

The Type 1 Opt-out is applied by default for all studies that are approved to use the service.
 Following agreement with the profession, this has been implemented in a way that would allow the Type 1 Opt-out (and any other) to be set aside in a future pandemic, or national emergency, and with the support of the profession.

Instructing your clinical system supplier

GP practices will have time between July and Early September to instruct their system suppliers to make their GP data available to the service. *Practices using the Medicus clinical system are out of scope.*

TPP (SystmOne) and Optum (EmisWeb) will provide for a button to allow practices to confirm their acceptance of the DPN, as per the system menus below:



SystmOne

Setup → Users & Policies → Organisation Preferences → OpenSAFELY (or use search bar)



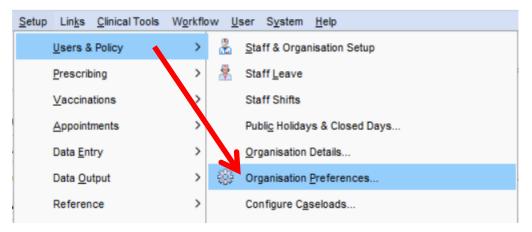
EmisWeb

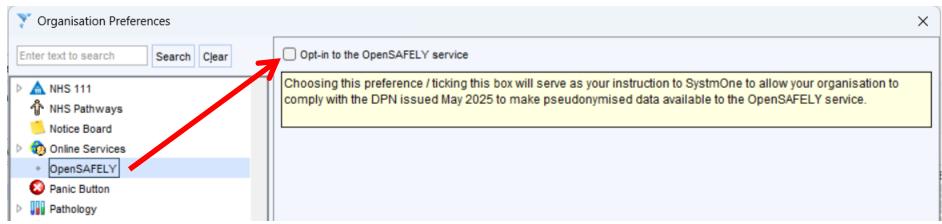
Configuration → Data Sharing Module Search for "NHS England OpenSAFELY Data Analytics Service"

TPP and Optum will provide regular reports to NHS England; this information will allow NHS England to support practices to meet their legal obligation to comply with the DPN.

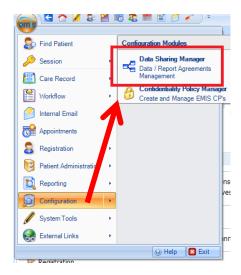
The collection, and sharing of these reports with NHS England, has the support of the BMA and RCGP representatives of the Joint GP IT Committee.

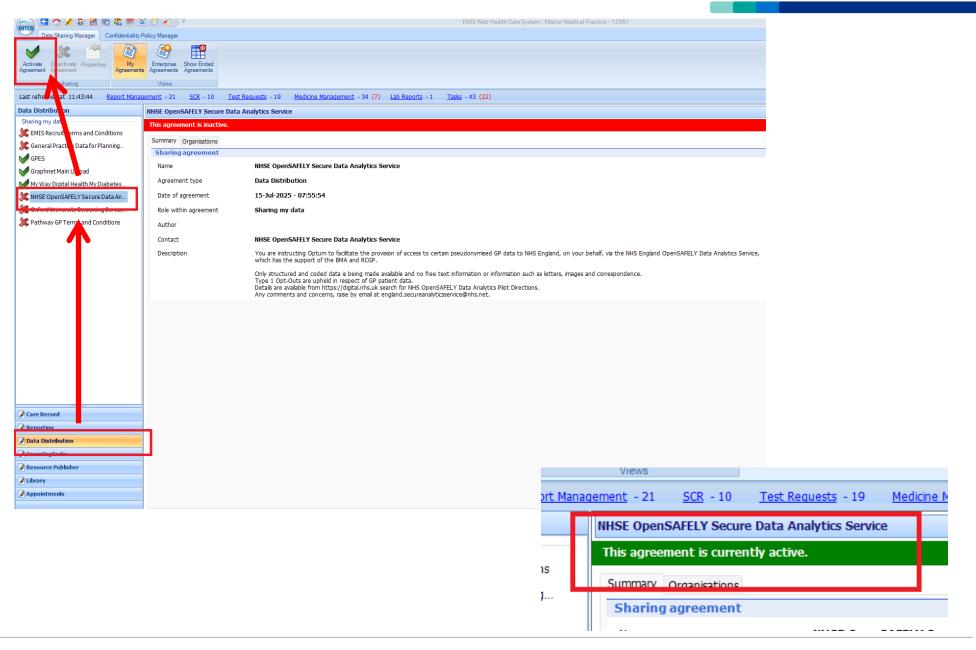












Documentation Suite

Document Name	Explainer (short form)
1 Directions Letter	Letter from Secretary of State instructing NHS England to implement an information system
2 Requirement Specification	Documents the specified purposes and mechanisms to be used to process the data, including the governance requirements
3 Data Processing Notice (DPN)	Formal notice requiring data from data controllers (i.e. GP practices) to be provided to NHS England for the purposes in line with the Direction
4 Data Protection Impact Assessment	Documented demonstration of compliance with Data Protection Law
5 Transparency Notice	Documented demonstration of compliance with Data Protection Law and that the processing of data is fair
6 GP Communications Letter 1 of 2	NHS England letter to raise awareness amongst general practice on the new Directions and DPN.
7 GP Communications Letter 2 of 2	NHS England letter to general practices notifying Directions and documentation is released and six-week review and acceptance period has started.
8 GP Communications – IG Portal, FAQ's	List of common/frequently asked questions, including the template GP DPIA



Any further comments, questions, or concerns, please email the dedicated mailbox: england.secureanalyticsservice@nhs.net

Thank You

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