

Data Provision Notice

OpenSAFELY COVID-19 Service

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Contents

Background	3
Purpose of this Data Provision Notice	3
Benefits	4
Legal basis for collection, analysis, publication and dissemination	5
Organisations consulted	5
Scope of the collection	6
Form and manner of the collection	7
Period of the collection	7
Data quality	7
Burden of the collection	8
Appendix 1	9
Appendix 2	9
Appendix 3	12

Background

The OpenSAFELY COVID-19 service (referred to as the **Service**) provides a secure analytics service for Approved Users (academics, analysts and data scientists) to access GP and NHS England pseudonymised patient data for COVID-19 research, COVID-19 clinical audit, COVID-19 service evaluation and COVID-19 health surveillance purposes (**COVID-19 Purposes**¹). The Service is currently operated by NHS England in collaboration with the Bennett Institute and The Phoenix Partnership (**TPP**), or Egton Medical Information Systems (**EMIS**) (the **GP System Suppliers**).

The Service (which functions as a Trusted Research Environment) uses OpenSAFELY open-source software tools (**OpenSAFELY Platform**), which were developed by the Bennett Institute in collaboration with the Electronic Health Record research group at London School of Hygiene and Tropical Medicine, NHS England, and the GP System Suppliers. The Service is designed to keep patient data confidential: users write analysis code away from the patient data and test it on dummy data; the Service then automates the running of code (the **Queries**) to generate intermediate pseudonymised patient level data sets (**Intermediate Outputs**) and then final anonymous aggregated outputs (the **Aggregated Outputs**).

The Service uses the OpenSAFELY Platform to run Queries on pseudonymised GP and NHS England patient data which is held within the GP system suppliers' data environments. The list of NHS England pseudonymised data sets held within the Service is set out in [Appendix 2](#).

Users only have access to the Aggregated Outputs generated by their Query. These Aggregated Outputs are released outside the GP System Suppliers' secure environment only after disclosure controls have been applied within the GP System Suppliers' secure environment and the results reviewed and cleared by trained output-checkers. All actions in the Service are logged in public, in real-time and all Queries are logged and published. No record level GP or NHS England data leaves the GP system suppliers' environment.

More information about how the Service operates is available on the OpenSAFELY website here: <https://www.opensafely.org/>

Purpose of this Data Provision Notice

The health and social care system needs to continue to take action to manage and mitigate the spread and impact of COVID-19. This includes ensuring that Approved Users can continue to use the Service for NHS England approved studies, to assist the health and care service's ongoing response to COVID-19.

NHS England and GP Practices were required, under notices issued by the Secretary of State under Regulation 3(4) of the Health Service (Control of Patient Information) Regulations 2002 (**COPI Regulations**), to process confidential patient information for COVID-19 purposes to create the Service. The last such notice was issued to NHS England, and GP Practices whose IT systems are supplied by the GP System Suppliers, on 2 May 2023 and will expire on 30 June 2023 (**COPI Notice**).

The statutory functions of NHS Digital transferred to NHS England under the Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions)

¹ The specific terms are defined here: https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf

Regulations 2023² on 1 February 2023. The effect of these Regulations was to transfer statutory functions of NHS Digital under directions previously issued to NHS Digital by the Secretary of State, to NHS England, together with associated statutory powers under the Health and Social Care Act 2012 (the **2012 Act**).

Under the COVID-19 Public Health Directions 2020 (**COVID-19 Directions**) NHS England has been directed by the Secretary of State to establish and operate such systems as are required for the collection and analysis of information for COVID-19 Purposes and to exercise such systems delivery functions of the Secretary of State, as may be requested by the Secretary of State from time to time for COVID-19 Purposes.

As the COPI Notice will expire on 30 June 2023, a new legal basis is required for the Service to continue. The Secretary of State has therefore requested that NHS England continue to operate the Service under the COVID-19 Directions and to exercise such systems delivery functions of the Secretary of State as are required to continue to operate the Service for the COVID-19 Purposes.

This Data Provision Notice is being issued to the GP Practices covered by the current COPI Notice, to require those GP Practices to continue to support the Service by continuing to provide:

- the Service with access to pseudonymised GP patient data:
 - for system integration activities, and
 - in order to run Queries against that data to produce the Intermediate and Aggregated Outputs for COVID-19 Purposes.

NHS England, as the operator of the Service (with access to the Intermediate Outputs for the purpose of carrying out statistical analysis, and to the Aggregated Outputs for the purpose of carrying out disclosure control checks, including dual review by trained output-checkers) will provide users who developed the Query with secure access to the Aggregated Outputs.

Benefits

The benefits of the continued operation of the Service include:

- meeting the increasing demand for access to data for COVID-19 Purposes from General Practice in a privacy enhancing, secure, efficient, safe, consistent, timely and transparent way,
- streamlined assessment and approval processes, aligned with the service functionality, providing transparent and rapid decision-making for users seeking to utilise the Service,
- reduced burden, responsibility, and risks on General Practice of individually administering multiple requests for access to data for COVID-19 Purposes,
- a simplified route for third parties to seek insight from GP data for COVID-19 Purposes and reduced burden on resources of GP System Suppliers and NHS England, and
- a Trusted Research Environment that protects privacy when accessing GP and NHS England data for analysis for COVID-19 Purposes without users having direct access to underlying record level data.

The use of the Service has enabled significant research into COVID-19 and will continue to do so. Examples of projects undertaken to date include:

² [The Health and Social Care Information Centre \(Transfer of Functions, Abolition and Transitional Provisions\) Regulations 2023 \(legislation.gov.uk\)](#)

- multiple ongoing and rapid analyses on vaccine effectiveness, safety, and coverage;
- research on the consequences of COVID-19 infection including cardiovascular outcomes and Long COVID;
- analyses of coverage and effectiveness for monoclonal antibody and antiviral treatments;
- health service changes in clinical activity and population impact during the pandemic;
- randomised COVID-19 trial follow-up;
- epidemiological transmission dynamics within households;
- observational pharmacoepidemiology to evaluate COVID-19 treatment candidates and safety issues;
- factors associated with risk of death from COVID-19;
- ethnicity and COVID-19; and
- comparative risks of different COVID-19 variants.

Further information about the projects carried out by the Service is published on the OpenSAFELY website here: <https://www.opensafely.org/research/>

Legal basis for collection, analysis, publication and dissemination

NHS England has been directed by the Secretary of State for Health and Social Care through the COVID-19 Directions under:

- section 254 of the Health and Social Care Act 2012, to establish and operate such systems as are required for the collection and analysis of information for COVID-19 Purposes, such systems are to be known as COVID-19 Public Health Information Systems; and
- regulation 32 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (the Regulations), to exercise such system delivery functions of the Secretary of State as may be requested by the Secretary of State from time to time for COVID-19 Purposes.

The Secretary of State has written to NHS England to request NHS England to continue to operate the Service as a COVID-19 Public Health Information System under paragraph 3.1 of the COVID-19 Directions and to exercise such systems delivery functions of the Secretary of State as are required to continue to operate the Service for the COVID-19 Purposes, subject to a number of safeguards set out in the letter. The letter is at [Appendix 3](#).

The safeguards required reflect the privacy safeguards already built within the Service but provide transparency and clarity over the requirements which need to be met by NHS England in continuing to deliver the Service under a new legal basis.

Organisations consulted

NHS England has, as required under section 258 of the Health and Social Care Act 2012, consulted with the following:

- Department of Health and Social Care (DHSC), as directing organisation
- The British Medical Association (BMA)
- The Royal College of General Practitioners (RCGP)

- The BMA and RCGP Joint GP IT Committee
- The National Data Guardian for Health and Social Care
- Interim Data Advisory Group which replaced Independent Group Advising on the Release of Data (IGARD) (and is in place until the formal terms of reference for the Advisory Group on Data (AGD) are formalised)
- OpenSAFELY Oversight Board
- Representatives of patients including Understanding Patient Data, Healthwatch England, Health Data Research UK patient and public involvement and engagement group, Use My Data, and a small sample of GP patient participation groups via the monthly GP Data Patient and Public Engagement and Communications Advisory Panel
- GP System Suppliers
- The Data Alliance Partnership Board (DAPB), which includes representatives from the Department of Health and Social Care, The National Institute for Health and Care Excellence, NHS England
- Information Commissioner's Office (ICO).

Scope of the collection

Under section 259(1)(a) of the 2012 Act, this Notice is served in accordance with the procedure published as part of the NHS England duty under section 259(8), on the following:

- All General Practices across England using TPP and EMIS GP health record systems.

Under section 259(5) of the 2012 Act, these General Practices must comply with the Form, Manner, and Period requirements below.

The pseudonymised record level data processed by the Service to deliver Intermediate and Aggregated Outputs contains structured and coded data only. It does not contain free text or information such as letters, images, and correspondence. It includes:

- Demographic information (age, sex, area of residence, ethnicity),
- Clinical information pertaining to COVID-19 care and outcomes,
- Clinical information pertaining to wider health conditions, medication, allergies, physiological measures (e.g. BMI), prior blood tests and other investigation results, and other recent medical history (e.g. smoking status).

The patient population made available within the Service for analysis is defined as all patients EXCEPT:

- Patients who have no period of registration (in a TPP or EMIS practice) after 1 January 2009 or who died before 1 January 2009 (year of Swine Flu Pandemic).

This means that for each system supplier if there has been any period of registration after 1 January 2009 then all the patient's data from the last practice with that system supplier is available to the Service for analysis, irrespective of the patient's current registration status.

- Subject to the transitional arrangements outlined below, patients who have registered a Type 1 Opt-out with their GP Practice. Notwithstanding that no identifiable patient data leaves the GP System Suppliers' secure environment through the operation of the

Service, Type 1 Opt-outs will be respected by the Service. This is consistent with other NHS England GP data collections directed under s254 of the 2012 Act, for planning and research purposes.

For this patient population, all coded GP patient data will be made available for analysis, except the following codes in these reference sets:

- SNOMED Refset for 'General Practice summary data sharing exclusion for gender related issues' 999004371000000109
- SNOMED Refset for 'General Practice summary data sharing exclusion for assisted fertility' 999004351000000100
- SNOMED Refset for 'General Practice summary data sharing exclusion for termination of pregnancy' 999004361000000107
- All children codes of the SNOMED code 118199002 'Finding related to sexuality and sexual activity'.

The above restricted codes could be extended to adhere to NHS England and professional guidance.

Transitional arrangements will apply to permit existing approved and incomplete projects as of 30 June 2023, to complete their projects before records with a Type 1 Opt-out are removed from the pseudonymised GP data used by the Service. This transitional arrangement will only apply to those projects where the removal of those records would prejudice the completion of the approved project.

The list of existing approved projects subject to this transitional arrangement will be published and maintained here: <https://www.opensafely.org/approved-projects/>

Form and manner of the collection

The data to be collected by NHS England is the Intermediate and Aggregated Output from each Query which has been run through the Service, in relation to an approved project. Only the Aggregated Output will be released from the GP System Supplier environment as part of the Service, and only after disclosure control checks have been applied (including dual review by trained output-checkers).

Period of the collection

The Service will be delivered under the COVID-19 Directions from 1 July 2023 and will be subject to an annual review.

Data quality

The Service supports short data reports, which provide a carefully documented source of information on data quality that is beneficial to all users of NHS data. These cover four key areas:

- Clinical reports describing how a specific clinical area is recorded in NHS data.
- Demographic reports describing population characteristics and how they can be identified.
- Administrative reports describing patterns in NHS data.

- Methodological reports describing data processing techniques for NHS data.

Burden of the collection

NHS England has a statutory duty under section 253(2) of the Act to seek to minimise the burden it imposes on others. In seeking to meet these obligations in relation to this Service, the Service has been designed to reduce burden, responsibility, and risks on General Practice of individually administering multiple requests for access to data, through NHS England continuing to operate the Service in collaboration with the Bennett Institute.

As this is an existing Service which is being continued, there is no additional burden on General Practices as a result of the change of legal basis.

In support of its obligation under 253(2) of the Act, NHS England has an assessment process to validate and challenge the level of burden incurred through introducing new data collections. This process is conducted by the Data Standards Assurance Service (DSAS) which assures burden assessment evidence as part of the overarching Data Alliance Partnership Board (DAPB) approval process.

A formal burden assessment was not carried out for this Service when it was established under the COPI Notices. As the legal basis for this Service is now changing, a burden assessment will now be conducted by the DSAS on behalf of the DAPB.

Appendix 1

OpenSAFELY Service – Usage to date

As of June 2023, 155 projects have been approved to use the Service and are listed here: <https://www.opensafely.org/approved-projects/>.

All Queries are logged and published in real-time: <https://jobs.opensafely.org/>

Reports produced by these approved projects are published here: <https://www.opensafely.org/research/> and <https://reports.opensafely.org/>.

The organisations which have received approval for utilising the Service are listed here: <https://www.opensafely.org/approved-projects/>

Only Approved Users can access the Service, under a signed NHS England OpenSAFELY Data Access Agreement. Users are considered as Approved Users following the ONS/UK Data Service process described on their websites. Applicants/Users attend a course and must pass an exam to be accredited. There is a public register of individuals who have been accredited (a list can be downloaded from the UK Statistics Authority website).

Appendix 2

The list below identifies all of the NHS England data sets which can be analysed alongside GP data through the Service as of 11 April 2023.

For an up-to-date list see the website here: <https://docs.opensafely.org/data-sources/>

Originating source of the data set ³	Content
NHS England	COVID-19 patient notification service (CPNS)
NHS England	SUS data (APCS, ECDS, OPA)
NHS England	HealthCare Worker status / flag (Via NIMS/Pinnacle)
NHS England	Second generation surveillance system (SGSS) SGSS_AllTests_Negative SGSS_AllTests_Positive SGSS_Negative

³ NHS England enters into a data sharing agreement with external organisations for them to share the data with NHS England to be made available through the Service

Originating source of the data set ³	Content
	SGSS_Positive
NHS England	Master Patient Index (MPI) with frailty flag data mart which includes pseudo UPRN data
NHS England	Bluteq data recording C19 antiviral / monoclonal antibody treatment for high-risk patients
NHS England	Waiting list data WL_ClockStops WL_Diagnostics WL_OpenPathways
NHS England	High-Cost Drugs
ONS	Patient data from ONS Death records (since Feb 2020)
ONS	COVID-19 infection survey data
Intensive Care National Audit & Research Centre (ICNARC)	ICNARC Case Mix Programme data
University of Oxford	ISARIC WHO Clinical Characterisation Protocol for Severe Emerging Infections UK (CCP-UK)
UK Kidney Association's Renal Register	Renal Register
University of Leicester and University of Edinburgh	PHOSP – Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes (PHOSP-COVID)

Originating source of the data set³	Content
King's College London*	Demographic; CSS biobank long COVID questionnaire; CSS biobank lab results (COVID-19 antibody tests); Zoe COVID symptom study app data.
London School of Hygiene and Tropical Medicine (OpenPROMPT)	Patient questionnaire data demographic, symptoms, quality of life, productivity, experience of COVID

* Data Sharing agreement signed but data not yet available to the Service

Appendix 3

Amanda Pritchard
Chief Executive Officer
NHS England

1st June 2023

Dear Amanda,

Establishment of the OpenSAFELY COVID-19 Service as a COVID-19 Public Health Information System

Background

NHS England has been directed by the Secretary of State under the COVID-19 Public Health Directions 2020^{[\[1\]](#)} (**COVID-19 Directions**) to establish and operate such systems as are required for the collection and analysis of information for COVID-19 Purposes and to exercise such systems delivery functions of the Secretary of State, as may be requested by the Secretary of State from time to time for **COVID-19 Purposes** (as set out below).

COPI Notice & Establishment of OpenSAFELY COVID-19 service

NHS England and GP Practices were required, under notices issued under regulation 3(4) of the Health Service (Control of Patient Information) Regulations 2002 (**COPI Regulations**), to process confidential patient information for **COVID-19 Purposes**. The last such notice was issued to NHS England, and GP Practices whose IT systems are supplied by The Phoenix Partnership (**TPP**) or Egton Medical Information Systems (**EMIS**) (the **GP System Suppliers**), on 02 May 2022, which expires on 30 June 2023.

Under this COPI Notice (and earlier notices issued under the COPI Regulations) the OpenSAFELY COVID-19 service (referred to as the **Service**) was established. This provides a secure analytics service for users, approved by or on behalf of NHS England (**Approved users**) to run queries on GP and NHS England pseudonymised patient data for **COVID-19 purposes** (as set out below).

Continuation of OpenSAFELY Service as a COVID-19 Public Health Information System

The health and social care system needs to continue to take action to manage and mitigate the spread and impact of COVID-19. This includes ensuring that Approved Users can continue to use the Service, to assist the health and social care system's ongoing response to COVID-19.

I am therefore requesting NHS England to continue to operate the Service as a COVID-19 Public Health Information System under paragraph 3.1 of the COVID-19 Directions and to

exercise such systems delivery functions of the Secretary of State as are required to continue to operate the Service, in accordance with the following safeguards:

- The Service should enable Approved Users to run queries against pseudonymised GP and NHS England patient data held by the GP System Suppliers, within the GP System Suppliers' secure environment, through the OpenSAFELY technology.
- The use of the Service, and the purpose of running the queries and obtaining the outputs, should be for COVID-19 research^[2], COVID-19 clinical audit, COVID-19 service evaluation and COVID-19 health surveillance^[3] purposes only (**COVID-19 Purposes**).
- The Service should not permit identifiable patient data to leave the GP System Suppliers' environment and therefore the results of all queries disclosed to Approved Users should be in the form of aggregate and anonymous data only.
- NHS England should ensure that the Service should not enable Approved Users to have direct access to the underlying pseudonymised GP and NHS England data, which should also remain in the GP System Suppliers' secure environment.
- Notwithstanding the above, and subject to the transitional arrangements specified below, the Service should exclude records of patients who have exercised a Type 1 opt out for planning and research purposes.
- Transitional arrangements should be put in place to permit existing approved projects as of 30 June 2023 which are incomplete, to complete their projects before records with a Type 1 opt out are removed from the pseudonymised GP data, where to remove those records would in NHS England's opinion, prejudice the completion of the project. The list of existing projects subject to this transitional arrangement should be published.
- NHS England should ensure there should be no attempts by any Approved User or operators of the Service to re-identify any patients whose data is contained within the Service.
- The Service should be transparent in relation to how it operates and the analysis which is being carried out. As a minimum, NHS England should ensure that the following information is published in relation to each query:
 - information about the data, which is processed through the OpenSAFELY technology,
 - the code which is used to carry out the processing of a query,
 - the outputs of the processing from a query approved for publication,
 - the specific COVID-19 Purposes for which the outputs of the query will be used,
 - the names of the organisations and the analysis leads who are the Approved Users using the Service, and
 - the research and all reports which use the outputs from the analysis.
- The Service should be subject to an appropriate framework of audit and assurance to ensure that it is being operated in accordance with the safeguards set out in this letter.

The need for the continuation of the Service will be reviewed at least annually by the Secretary of State in consultation with NHSE, with the first review to be undertaken before 1st July 2024.

Your sincerely



Louise Greenrod
Deputy Director of Data Policy and Digital Oversight

For and on behalf of the Secretary of State for Health and Social Care

^[1] <https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notice/secretary-of-state-directions/covid-19-public-health-directions-2020>. The Directions were given by the Secretary of State to NHS Digital on 17 March 2020. NHS Digital was abolished, and its functions transferred to NHS England, with effect from 1 February 2023, by the Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98). By virtue of regulation 6, those Directions have effect as if references to the Health and Social Care Information Centre (or NHS Digital) were references to NHS England (and the Directions accordingly have effect as if given to NHS England).

^[2] “as defined in paragraph 3.1 of the [UK Policy Framework for Health and Social Care Research](#)

^[3] As defined in the https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf