



Department  
of Health &  
Social Care

Department of Health and Social  
Care

39 Victoria Street  
London SW1H 0EU

Sir James Mackey  
Chief Executive  
NHS England

09 June 2025

Dear Sir James,

## 1. NHS OpenSAFELY Data Analytics Service Pilot Directions 2025

- 1.1 I am writing on behalf of the Secretary of State for Health and Social Care (**the Secretary of State**) to give Directions to **NHS England**.
- 1.2 These Directions are given in exercise of the powers conferred by sections 254(1) and 304(9), (10) and (12) of the Health and Social Care Act 2012<sup>1</sup> (**the 2012 Act**) and sections 13ZC and 272(7) and (8) of the National Health Service Act 2006<sup>2</sup> (**the 2006 Act**).
- 1.3 The service enabled by these Directions is also operated by NHS England in the exercise of its powers under sections 1 and 2 and Chapter A1 of Part 2 of the 2006 Act and section 270 of the 2012 Act.
- 1.4 These Directions are to be known as the **NHS OpenSAFELY Data Analytics Service Pilot Directions 2025** and they come into force on the date after the day on which they are signed.

## 2. Requirement for these Directions

- 2.1 In accordance with section 254(2)(b) of the 2012 Act, the Secretary of State considers that it is in the interests of the health service in England or of the

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<sup>1</sup> 2012 c.7 (the 2012 Act). Relevant amendments were made by the Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98).

<sup>2</sup> 2006 c.41. Section 13ZC was inserted by section 45 of the Health and Care Act 2022 (c.31).

recipients or providers of adult social care in England for these Directions to be given.

2.2 In accordance with section 254(5) of the 2012 Act, the Secretary of State has consulted NHS England before giving these Directions.

2.3 In accordance with section 13ZC(5) of the 2006 Act, the Secretary of State considers these Directions to be in the public interest.

### 3. **Priorities, Policies and Non-Statutory Guidance**

In exercising functions under these Directions, NHS England must have regard to such priorities, policies and non-statutory guidance<sup>3</sup> of the Secretary of State as the Secretary of State may notify in writing from time to time to NHS England.

### 4. **Background**

4.1 The OpenSAFELY COVID-19 Service was established under the COVID-19 Public Health Directions 2020<sup>4</sup> (**COVID-19 Public Health Directions**) in June 2023 and provides a secure data analytics service for users approved by or on behalf of NHS England, to run queries on pseudonymised General Practice (**GP**) and NHS England patient data for certain COVID-19 Purposes<sup>5</sup>.

4.2 Learning from the OpenSAFELY COVID-19 Service, it is considered that that the Service should be expanded on a pilot basis to enable the Service to be operated for purposes that are wider than the COVID-19 Purposes, as described below.

### 5. **Purpose**

5.1 The purpose of these Directions (**Purpose**) is to enable NHS England to establish a secure data analytics service (the **Service**) using the OpenSAFELY technology, namely a service for users approved by or on behalf of NHS England (**Approved Users**) to run queries on pseudonymised GP and NHS England patient data held by GP IT system suppliers (**GP System Suppliers**) within the GP System Suppliers' secure environments and obtain outputs, for the purposes set out in paragraph 5.2 below.

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<sup>3</sup>In addition, NHS England has a duty to have regard to [statutory guidance issued by the Secretary of State under section 274A of the 2012 Act: NHS England's protection of patient data, 23 May 2023](#), as the same may be updated from time to time.

<sup>4</sup> [COVID-19 Public Health Directions 2020 - NHS England Digital](#) ("the 2020 Directions"). Amendments were made by the Amendment to Covid-19 Public Health Directions 2020 given on 31 March 2020 and the Amendment No. 2 to the COVID-19 Public Health Directions 2020 given on 17 February 2022. The 2020 Directions were given by the Secretary of State to the Health and Social Care Information Centre (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, the 2020 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).

<sup>5</sup> See the letter from the Secretary of State to the Chief Executive of NHS England dated 1 June 2023 establishing the OpenSAFELY COVID-19 Service as a COVID-19 Public Health Information System.

5.2 The Service may only be operated and NHS England may only allow Approved Users to use it for such of the following purposes as are specified in the Requirements Specification (as referred to in paragraph 6.1 below):

- 5.2.1 clinical audit<sup>6</sup>;
- 5.2.2 service evaluation<sup>7</sup>;
- 5.2.3 health surveillance<sup>8</sup>;
- 5.2.4 research<sup>9</sup>;
- 5.2.5 evaluation of the Service; and
- 5.2.6 health and social care policy, planning and commissioning purposes and public health purposes where agreed on a project specific basis by or on behalf of:
  - the Department of Health and Social Care,
  - NHS England, and
  - a nominated representative of each of the Royal College of General Practitioners and the British Medical Association on behalf of the Joint GP IT Committee,

but excluding the purposes in paragraph 5.3 below.

5.3 The purposes excluded for the purposes of paragraph 5.2 above are COVID-19 research, COVID-19 clinical audit, COVID-19 service evaluation and COVID-19 health surveillance, which are purposes already met by the COVID-19 Service established and operated under the COVID-19 Public Health Directions, for so long as that service is in operation.

## 6. Establishing and operating information systems

6.1 The Secretary of State directs NHS England to establish and operate a system for the collection and analysis of the information set out in the NHS OpenSAFELY Data Analytics Service Pilot Requirements Specification version 1 as published with these Directions, as updated periodically by the Secretary of State in consultation with NHS England and the Joint GP IT Committee, representing the GP profession (**the Requirements Specification**).

6.2 The system established under paragraph 6.1 above will be known as the **NHS OpenSAFELY Data Analytics Service Pilot Information System**.

6.3 In exercising functions under these Directions, NHS England must act in accordance with the Requirements Specification, the safeguards referred to

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<sup>6</sup> As defined in the [https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable\\_Oct2022.pdf](https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf)

<sup>7</sup> As defined in the [https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable\\_Oct2022.pdf](https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf)

<sup>8</sup> As defined in the [https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable\\_Oct2022.pdf](https://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2022.pdf)

<sup>9</sup> As defined in paragraph 3.1 of the [UK Policy Framework for Health and Social Care Research](#)

in paragraph 7 below, and generally in such a way as to achieve the Purpose.

## 7. Safeguards

In exercising functions under these Directions NHS England must operate the Service in accordance with the following safeguards:

- 7.1 The Service should not permit identifiable patient data to leave the GP System Suppliers' environments and therefore the results of all queries disclosed to Approved Users should be in the form of aggregate and anonymous data only.
- 7.2 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 remain in the GP System Suppliers' secure environments.
- 7.3 Subject to paragraph 7.4 below, the Service should exclude records of patients who have exercised a Type 1 opt out<sup>10</sup> for planning and research purposes.
- 7.4 Records of patients who have registered a Type 1 opt out are not to be excluded where the Service is used for public health purposes and where it is agreed on a project specific basis under paragraph 5.2.6 that a Type 1 opt out is not to be upheld.
- 7.5 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.
- 7.6 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:
  - 7.6.1 information about the data, which is processed through the OpenSAFELY technology,
  - 7.6.2 the code which is used to carry out the processing of a query,
  - 7.6.3 the outputs of the processing from a query approved for publication,
  - 7.6.4 the specific Purposes for which the outputs of the query will be used,
  - 7.6.5 the names of the organisations and the analysis leads who are the Approved Users using the Service, and

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<sup>10</sup> Type 1 objections recorded in GP records represent patients' choice to opt out of their confidential patient information being used for purposes beyond their individual care without their explicit consent.

7.6.6 the research and all reports which use the outputs from the analysis.

7.7 The Service should be subject to an appropriate framework of audit and assurance to ensure that it is being operated in accordance with these safeguards and the Directions.

## 8. **Service Levels etc**

In exercising functions under these Directions, NHS England must act in accordance with the service levels, support and monitoring requirements, and the reporting and governance requirements notified by the Secretary of State in writing to NHS England as at the date these Directions come into force, or as those requirements are amended and notified by an authorised officer of the Department for Health and Social Care on behalf of the Secretary of State in writing to NHS England from time to time.

## 9. **Publication**

For the purposes of section 260(1) and (2)(d) of the 2012 Act, certain of the Information might be specified in the Requirements Specification as not for publication (**Non-Published Data**) under section 260(2)(d) of the 2012 Act (and must not be published)<sup>11</sup>.

## 10. **Fees and Accounts**

NHS England must keep proper accounts, and proper records in relation to the accounts, in connection with these Directions.

## 11. **Duration**

These Directions cease to have effect on 31st March 2027 or such other date, if any, as the Secretary of State notifies to NHS England by a further direction.

## 12. **Review of these Directions**

These Directions will be reviewed from time to time. Any change to the approach taken in these Directions will only be made after consultation with NHS England and the Joint GP IT Committee, representing the GP profession.

Yours sincerely



Signed by authority of the Secretary of State

Date signed: 09 June 2025

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<sup>11</sup> Such information is specified as information falling within section 260(2)(d) and the prohibition in section 260(1) on publishing information accordingly applies to it.