



Department
of Health &
Social Care

Department of Health and Social
Care
39 Victoria Street
London SW1H 0EU

Sir James Mackey
Chief Executive
NHS England

24th March 2026

Dear Sir James,

1. The NHS DigiTrials Recruitment Service Directions 2026

- 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) to (12) of the Health and Social Care Act 2012¹ (**the 2012 Act**) and sections 13ZC and 272(7) and (8) of the National Health Service Act 2006² (**the 2006 Act**).
- 1.3 The service enabled by these Directions is operated by NHS England in the exercise of its powers under sections 1, 1H, 2 and Chapter A1 of Part 2 of the 2006 Act.
- 1.4 These Directions are to be known as the **NHS DigiTrials Recruitment Service Directions 2026** and come into force on the date after the day on which they are signed.

2. Need 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

¹ 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).

² 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 guidance³ of the Secretary of State as the Secretary of State may notify in writing from time to time to NHS England.

4. **Purpose**

4.1 The purpose of these Directions (the Purpose) is to enable NHS England to enhance its support for health and life sciences research by implementing and operating the NHS DigiTrials Recruitment Service (the Service). The Service will:

4.1.1 Aim to enhance the efficiency and effectiveness of clinical trial recruitment across the UK by identifying appropriate cohorts to be invited to take part in research, using data which has already been collected by NHS England;

4.1.2 Collect, analyse and link data required to support requesting organisations in the use of the Service; and

4.1.3 Enable the use of data obtained as part of delivering the Service, including through analysis and linkage of data, to support service delivery management, monitoring and improvement.

5. **Establishing and operating information systems**

5.1 The Secretary of State directs NHS England to establish and operate a system for the collection and analysis of the information described in the DigiTrials Recruitment Service Requirements Specification version 1 (as published with these Directions) as updated periodically by the Secretary of State in consultation with NHS England (the **Requirements Specification**).

5.2 The Secretary of State directs NHS England to analyse the information which NHS England obtains by complying with these Directions (the **Information**), as may be required by the Secretary of State or as NHS England considers necessary to achieve the Purpose.

5.3 Such analysis includes:

5.3.1 analysis by reference or linkage to any other information described in the Requirements Specification(s);

³In 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.

5.3.2 analysis for data quality purposes, including undertaking comparison and consistency analysis of the same or similar information obtained by complying with other directions under section 254 of the 2012 Act;

5.3.3 any other analysis of the information as NHS England considers appropriate to maintain data quality, accuracy and consistency in relation to the Information.

5.4 In exercising functions under these Directions, NHS England must act in accordance with the Requirements Specification(s) and generally in such a way as to achieve the Purpose.

6. 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 of Health and Social Care on behalf of the Secretary of State in writing to NHS England from time to time.

7. Fees and Accounts

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

8. Duration

NHS England must exercise functions under these Directions until they are revoked by a further direction in writing by an authorised officer of the Department of Health and Social Care on behalf of the Secretary of State.

9. Review of these Directions

These Directions will be reviewed from time to time. Any amendments to the Directions or the Requirements Specification(s) will only be made after consultation with NHS England.

10. Revocation

10.1 The following directions are revoked:

10.1.1 Pilot NHS DigiTrials Recruitment Support Services Directions 2021⁴;

⁴ The Directions were given by the Secretary of State to the Health and Social Care Information Centre (NHS Digital) on 30 July 2021. 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 NHS Digital were references to NHS England (and the Directions accordingly have effect as if given to NHS England). A hard copy of the Directions can be obtained from Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU

10.1.2 Amendment to the Pilot NHS DigiTrials Recruitment Support Services Directions 2021⁵;

10.1.3 Pilot NHS DigiTrials Recruitment Support Services (Amendment 2) Directions 2023⁶; and

10.1.4 Pilot NHS DigiTrials Recruitment Support Services (Amendment No. 3) Directions 2025⁷.

Yours sincerely



Signed by authority of the Secretary of State

Date signed: 24th March 2026

⁵ The Directions were given by the Secretary of State to the Health and Social Care Information Centre (NHS Digital) on 6 December 2022. 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 NHS Digital were references to NHS England (and the Directions accordingly have effect as if given to NHS England). A hard copy of the Directions can be obtained from Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU

⁶ The Directions were given by the Secretary of State to NHS England on 21 September 2023. A hard copy of the Directions can be obtained from Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU

⁷ The Directions were given by the Secretary of State to NHS England on 24 March 2025. A hard copy of the Directions can be obtained from Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU