



Simon Bolton
Chief Executive
NHS Digital
7 & 8 Wellington Place
Leeds
West Yorkshire
LS1 4AP

30 July 2021

Dear Simon

1. Pilot NHS DigiTrials Recruitment Support Services Directions 2021

- 1.1 I am writing on behalf of the Secretary of State for Health and Social Care (**the Secretary of State**) to provide Directions to the Health and Social Care Information Centre, known as and hereafter referred to in these Directions as NHS Digital.
- 1.2 These Directions are given in exercise of the powers conferred by sections 254(1) and (6), section 260(2)(d), section 261(2)(e) and section 304(9), (10) and (12) of the Health and Social Care Act 2012¹ (**the 2012 Act**) 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 2013² (**the Regulations**).
- 1.3 In exercising the activities and functions described in these Directions, NHS Digital must have regard to such priorities, policies, advice or guidance of the Secretary of State as the Secretary of State may notify in writing from time to time to NHS Digital.
- 1.4 These time limited Directions are to be known as the **Pilot NHS DigiTrials Recruitment Support Services Directions 2021** and come into force on the date signed.

¹ 2012 c.7

² S.I. 2013/259

2. Purpose

- 2.1 The purpose of these Directions (**Purpose**) is to enable NHS Digital to enhance its support for health and life sciences research, by developing new elements of an NHS Data-Enabled Clinical Trials Service (NHS DigiTrials). This will help set the UK on a pathway to become a world-leader in clinical research - bringing health and economic benefits of research to UK citizens as well as to the NHS, including supporting recovery COVID-19³.
- 2.2 Specifically, these Directions enable NHS Digital to provide the Pilot NHS DigiTrials Recruitment Support Service to a maximum of four clinical research trials to test the concept. This will use routinely collected NHS data to:
 - 2.2.1 widen the diversity of those given the opportunity to participate in clinical trials,
 - 2.2.2 enable faster, more efficient and effective trial set-up,
 - 2.2.3 increase overall recruitment to clinical trials.
- 2.3 Although aimed primarily at clinical trials, NHS DigiTrials Services may be used to support any approved healthcare research that meets the definition as set out in the [UK Policy Framework for Health and Social Care Research](#),⁴ which must in turn be overseen by the [Health Research Authority](#).⁵ All approved healthcare research that meets this definition may also be reviewed by a Research Ethics Committee.
- 2.4 The elements of the Pilot NHS DigiTrials Recruitment Support Services relevant to this Direction (the **Services**) are:
 - 2.4.1 A service to identify individuals who are suitable for invitation to participate in clinical research projects that aim to improve health outcomes, once approved by the Health Research Authority.⁶ NHS Digital will be responsible for developing capability to find potential participants by analysing and linking data it holds as Controller⁷ and procuring or developing appropriate approaches for finding potential participants.
 - 2.4.2 This Direction does not provide a legal basis to process data on behalf of, or to disseminate data to, NHS DigiTrials customers. All data processing to provide the NHS DigiTrials services must be supported by a clear legal basis e.g., the trial may be supported by an approval under section 251 of the NHS Act 2006, patient consent or

³ [Hancock: transforming the UK into a life sciences superpower - GOV.UK \(www.gov.uk\)](#)

⁴ <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

⁵ <https://www.hra.nhs.uk/>

⁶ The invitation service is not covered by these Directions, please see paragraph 2.5.

⁷ As defined in Article 4(7) of the UK General Data Protection Regulation 2016

any other relevant legislation, as well as an appropriate legal basis under the UK General Data Protection Regulations 2018 and Data Protection Act 2018.

2.4.3 NHS Digital will be responsible for onboarding, processing, linking and making data available for use in the Services, including meeting bespoke needs for specific trials as far as possible and appropriate. This includes the development of linked data sets as required to deliver the NHS DigiTrials services that brings together a more holistic, patient centric view of data already held in NHS Digital.

2.5 The Services are more particularly described in the Pilot NHS DigiTrials Recruitment Support Services Directions 2021 Requirements Specification attached at Annex A to these Directions, which may be updated periodically (within the confines of the scope set out in these Directions) by NHS Digital and agreed in writing by an authorised officer of the Department of Health and Social Care on behalf of the Secretary of State (the **Requirements Specification**). The Requirements Specification sets out all elements of NHS DigiTrials, including those not covered by these Directions, to provide a fuller context for the operation of the Services.

3. **Establishing and operating information systems for the Pilot NHS DigiTrials Recruitment Support Services Directions data analysis and linkage**

3.1 In accordance with sections 254(1) and 254(6) of the 2012 Act, the Secretary of State directs NHS Digital to establish and operate a system for the analysis and linkage of information described in the Requirements Specification such system to be known as the Pilot NHS DigiTrials Recruitment Support Services Directions Information System.

3.2 Pursuant to the Secretary of State's England's powers under 254(1) and 254(6) of the 2012 Act, NHS Digital is directed to analyse and link data it holds as Controller⁸ where there is no restriction on the use of that data under existing directions , as may be requested by the Secretary of State or as NHS Digital determines is necessary to achieve the Purpose.

3.3 Such analysis referred to above includes:

3.3.1 analysis by reference or linkage to other data obtained by NHS Digital under any other direction under section 254 or a request made under section 255 of the 2012 Act, or any other lawful basis where NHS Digital is a controller of the other data, subject to any restrictions in the directions or statutory requests applicable to that data.

3.3.2 Analysis for data quality purposes, including undertaking comparison and consistency analysis of the same or similar information obtained through other information systems established by NHS Digital under

⁸ As defined in Article 4(7) of the UK General Data Protection Regulation 2016

any other direction under section 254 or request made under section 255 of the 2012 Act, and taking such steps as NHS Digital considers appropriate to maintain data quality, accuracy and consistency of information it has obtained under these Directions and across all information systems.

3.4 NHS Digital is directed to carry out the activities above in accordance with the Requirements Specification and generally in such a way as to enable and facilitate the Purpose described above. The Requirements Specification may be updated periodically (within the confines of the scope set out in these Directions) by NHS Digital and agreed in writing by the Secretary of State.

4. Systems delivery functions for the Pilot NHS DigiTrials Recruitment Support Services Directions 2021

In accordance with Regulation 32 of the Regulations, the Secretary of State directs NHS Digital to exercise such systems delivery functions of the Secretary of State as are necessary to enable and facilitate the Pilot NHS DigiTrials Recruitment Support Services Directions 2021 described in the Purpose.

5. Service Levels etc

The Secretary of State directs NHS Digital to exercise the functions described above 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 Digital 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 Digital from time to time.

6. Requirement for these Directions

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

6.2 In accordance with section 254(5) of the 2012 Act, NHS Digital has been consulted before these Directions have been given.

7. Publication

In accordance with section 260(2)(d) of the 2012 Act, NHS Digital is directed not to publish information that is specified as not for publication in the Requirements Specification.

8. Dissemination

8.1 In accordance with section 261(2)(e) of the 2012 Act, despite the prohibition on publication, NHS Digital may disseminate under section 261(1) of the

2012 Act the information it has obtained by complying with these Directions, where section 261(1) would otherwise not apply due to the restriction on publication, and where it would be lawful for NHS Digital to do so.

- 8.2 Any information collected as a result of, or obtained by complying with, these Directions may also be disseminated by NHS Digital in accordance with its discretionary powers under section 261 of the 2012 Act.

9. Fees and Accounts

- 9.1 In accordance with regulation 32(2)(a) of the Regulations, the Secretary of State may make payments to NHS Digital for things done in connection with the exercise of the systems delivery functions referred to above.
- 9.2 NHS Digital must keep proper accounts, and proper records in relation to the accounts, in connection with the Pilot NHS DigiTrials Recruitment Support Services Directions 2021.

10. Duration

- 10.1 NHS Digital is directed to operate the Pilot NHS DigiTrials Recruitment Support Services Information System and undertake the system delivery function referred to above (the **Directed Functions**) until 31 December 2022 during which time the Service will be piloted by a maximum of four clinical research trials.
- 10.2 If additional time is required in order to commence or complete the pilot service, then a further direction or instruction will be issued, in writing by an authorised officer of the Department of Health and Social Care on behalf of the Secretary of State to extend the operation of the Directed Functions.
- 10.3 Where one of the Directed Functions is to cease before 31 December 2022, this will be by a further direction or instruction in writing by an authorised officer of the Department of Health and Social Care on behalf of the Secretary of State on reasonable notice to suspend and/or permanently cease the Directed Function. Such a written request will also contain a direction to revoke these Directions in accordance with the timescales and arrangements to be agreed with NHS Digital.

11. Review of these Directions

These Directions will be reviewed when the Requirements Specification is amended. This review will include consultation with NHS Digital.

Yours sincerely,



Signed by authority of the Secretary of State for Health and Social Care

Date signed: 30 July 2021

ANNEX – NHS DIGITRIALS SERVICES DIRECTIONS 2021

**Annex A - Pilot NHS DigiTrials Recruitment Support Services Directions 2021
Requirements Specification**