Data Sharing Audits: A Guide for Data Recipients

Ensuring recipients of our confidential information are committed to its safe handling

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Information and technology for better health and care

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1 Introduction

1.1 Why is NHS Digital conducting data sharing audits?

The Health and Social Care Information Centre (also known as NHS Digital) has a legal duty to maintain the confidentiality, safety, security and integrity of all personal and patient data it holds and disseminates. This duty is defined through the Health and Social Care Act 2012, the General Data Protection Regulation (GDPR), the Data Protection Act 2018 (DPA 2018) and common law duty of confidentiality.

NHS Digital provides confidential information to a wide variety of organisations to support specific purposes. Each data dissemination is subject to a data sharing framework contract and data sharing agreement. The purpose of a data sharing audit is to ensure that the data recipient is meeting the requirements of the data sharing framework contract and data sharing agreement, along with other relevant standards and guidelines.

NHS Digital audits data recipients to ensure that confidential information is handled appropriately.

1.2 Who is this guide for?

This guide is designed for all recipients of data from NHS Digital under a data sharing framework contract and data sharing agreement for the purposes of benefitting health and social care. This guide is designed to provide an overview of NHS Digital's management of the data sharing audit process so that:

- data recipients understand how the NHS Digital Audit Team will approach an audit
- there is enhanced public trust in one of the ways in which NHS Digital assures the release of data provided to organisations.

Within the context of this guide the term "data recipient" also encompasses any processors or third-parties engaged as part of a data sharing agreement. This will also include undeclared parties in the data sharing agreement that also receive the data.

2 The Data Sharing Audit Process

This section guides the data recipient through each stage of a data sharing audit, though in certain instances some stages may not apply.

2.1 The Audit Team

NHS Digital has established an independent audit function that is separate from the Data Access Request Service (DARS).

Audit Team personnel are suitably experienced and hold relevant international and/or industry recognised auditing and technical qualifications.

For certain audits, the Audit Team may include Subject Matter Experts from other teams within NHS Digital to ensure the necessary balance of expertise and competence.

2.2 Selecting a data recipient for audit

A data recipient can be selected for audit by DARS:

- to seek confidence in its ability to handle data securely prior to the receipt of data
- whilst in the possession of data supplied by NHS Digital
- following destruction of the supplied data.

The Audit Team is then commissioned by DARS to audit the selected data recipients.

The Audit Team may also independently identify a data recipient from available data dissemination lists. Such audits would be confirmed with DARS and follow the same process described below.

2.3 Types of data sharing audits

A data sharing audit will fall under one of the following four types:

1. **Routine** - audit of a data recipient already in receipt of data which will look at the full range of topics listed in section 2.4.
2. **Focused** - audit that concentrates on specific elements, for example, data destruction. The onsite visit will generally be shorter than for a routine audit.
3. **Pre-release** - audit prior to any release to ensure that the data recipient can handle data appropriately. This type of audit will normally consider the topics listed in section 2.4 except for use and benefits of data.
4. **Heightened concern** – audit to consider concerns raised within NHS Digital. In certain circumstances the audit will be unannounced. The scope of the audit will be dependent on the nature of the concern raised.

The type of audit will be declared in the notification letter and confirmed at the onsite audit, unless it is an unannounced audit.

The reporting process described below will be the same for all audits.

Depending on the nature of the findings identified, a post audit review may be conducted, see section 2.21.

2.4 Audit scope

The audit scope will cover the data recipient's management and use of data provided by NHS Digital.

The six scope areas usually considered by the Audit Team are:

- information transfer
- access control
- use and benefits of data
- data destruction
- risk management
- operational management and control.

The data recipient will be advised when the scope deviates from the above.

The audit will seek to determine whether:

- the data recipient is adhering to, or could adhere to, the requirements of the data sharing framework contract and data sharing agreement(s). An example contract and agreement can be found at https://digital.nhs.uk/services/data-access-request-service-dars
- the data handling activities performed by the data recipient pose an unacceptable risk to confidentiality or to NHS Digital
- the data recipient conforms to its own policies, processes and procedures.

An audit may also involve any data processor or third-party engaged by the data recipient to ensure that a complete understanding of the handling of the supplied data is obtained. The above checks will also apply to such parties.

Typical opening questions and types of evidence required related to the six scope areas are detailed in Appendix A.

2.5 Notifying a data recipient of an audit

Once a data recipient has been selected for an audit, the Lead Auditor will send a notification letter to the data recipient's main contact. This letter will be sent by email no less than 10 working days prior to the proposed audit date.

For an unannounced heightened concern audit, there will be no notification letter and no prior notice.

In exceptional circumstances the data recipient may seek an alternative date for the audit, which must be raised prior to the telephone call with the Audit Team, see section 2.6.

The Lead Auditor will provide a draft audit plan (Appendix B) and a document checklist (Appendix C) with the notification letter. The draft audit plan will meet the specific scope of the audit. The data recipient will review the draft audit plan and indicate the names of personnel that will attend each session.

2.6 Telephone Call

Following receipt of the notification letter, the Lead Auditor will arrange a call with the data recipient to discuss:

- the audit process
- any requested changes to the audit date
- the audit plan and who should attend from data recipient and any processor (see section 2.7)
- audit logistics, including location(s) for the audit
- documentation to be supplied by the data recipient prior to the on-site visit (see section 2.8)
- any requirement to visit a data centre or third-party including any processor.

2.7 Representatives the Audit Team will want to see onsite

The Audit Team will require access to managerial, operational and technical personnel who are able to cover the areas detailed in the scope and understand how data supplied by NHS Digital is processed.

The following table gives an overview of the key staff likely to be involved for each of the defined scope areas. The actual staff involved will depend on the roles and responsibilities undertaken in the organisation. Further representation may also be needed from third-parties including processors. It is essential that staff are present during the onsite visit who can answer the type of questions and provide the types of evidence detailed in Appendix A.

Scope Area	Typical representation
Information Transfer	Business Intelligence Staff involved in processing the data Information Security Information Technology
Access Control	Information Security Information Technology
Data Destruction	Information Security Information Technology
Operational Management and Control	Information Governance Human Resources
Use and Benefits	Business Intelligence Staff involved in processing data / producing outputs
Risk Management	Risk Management

Table 1: Key representatives for onsite visit

The Audit Team may also request to visit locations where data supplied by NHS Digital is being processed/stored. The data recipient will therefore need to make available personnel to escort the Audit Team during such visits.

If the data recipient is unsure which representatives are required or appropriate, this can be discussed during the telephone call with the Lead Auditor, see section 2.6.

2.8 Documents the Audit Team will want to see

Prior to the audit, relevant documentation shall be submitted to the Audit Team. A documentation checklist, Appendix C, will be provided with the notification letter for completion by the data recipient. As document names and content vary across organisations, it is the responsibility of the data recipient to indicate titles on the Documentation Checklist and supply the relevant material.

These documents will be used to supplement and inform the audit and will be reviewed at NHS Digital offices prior to the onsite visit. A finding may be included in the report when documents are not provided **prior** to the onsite visit without a reasonable justification.

2.9 Data processing statement

The personal data the Audit Team holds about a data recipient includes personal data provided to NHS Digital as part of the data application process in support of audit activities and on completed feedback questionnaires. This personal data will only be used for administrative and audit delivery purposes; it will not be supplied to any other party outside of the data sharing audit function. It may, however, be shared with an external audit organisation commissioned by NHS Digital to undertake audits on behalf of the Audit Team.

The Audit Team maintains an audit database which holds contact information and key milestone dates. Access to the database is limited to staff within the NHS Digital audit function.

All documentation supplied by, or on behalf of, a data recipient will be held securely by NHS Digital. Access is limited to the data sharing audit team and its support personnel and management team.

Material supplied by the data recipient will be retained in accordance with NHS Digital's records management retention schedule, GDPR, Data Protection Act 2018 (DPA 2018) and the Health and Social Care Act 2012.

For more details around how NHS Digital uses personal data, in line with GDPR, see https://digital.nhs.uk/about-nhs-digital/our-work/keeping-patient-data-safe/gdpr/gdpr-register

NHS Digital may receive requests under the Freedom of Information Act 2000 to disclose information in relation to an audit. Requests for information are looked at on a case by case basis by the appropriate team within NHS Digital. The team responsible for freedom of information requests may consult with the data recipient in question before responding to the request.

2.10 The onsite visit

The onsite visit will usually take two days and involve two auditors; the actual number of days and team members will be shown in the draft audit plan sent with the notification letter. The Audit Team will try to keep disruption to the data recipient to a minimum through the agreement of the audit plan.

Where the processor's location is different from the data recipient, the need to visit individual locations will be identified at the audit planning stage.

2.10.1 Arrangements for the onsite visit

The data recipient should provide a dedicated room, at each location identified in the audit plan, for the Audit Team to conduct interviews and review documentation / evidence. The Audit Team may also need to conduct information reviews or equipment checks in different areas of the facility. Internet access will be requested in advance, if required.

2.10.2 At the onsite visit

2.10.2.1 Opening meeting

The Audit Team will hold an opening meeting with appropriate data recipient representatives to explain the audit process. The meeting will provide the data recipient an opportunity to discuss any issues or concerns with respect to the audit process. The Audit Team may make minor changes to the audit plan timings at the opening meeting should the need arise.

2.10.2.2 Interviews and reviews

The Audit Team will conduct an evidence-based assessment of the data recipient's controls and environment where data resides. The Audit Team will undertake interviews of relevant staff, review documents, records and uses of data along with an inspection of implemented controls.

The questions asked and evidence gathered will relate to the audit scope and any special conditions of the data sharing agreement(s). There are some generic areas which are normally covered during an audit, examples of these areas are contained in Appendix A.

The most important elements of an audit are timely access to supporting evidence and to appropriate staff who answer questions openly, comprehensively and accurately.

The Audit Team will make and retain notes from interviews, observations and testing. Copies of any documentation not supplied prior to the audit visit may be requested for review by the Audit Team. Any documentation removed will be handled appropriately by the Audit Team as outlined in section 2.9.

2.10.2.3 Closing meeting

The Audit Team will hold a closing meeting with the data recipient's representatives to discuss the identified findings. The findings will be caveated if pre-existing material still needs to be provided.

The Auditor Team may conduct a further review of its notes after the onsite audit, which could identify new findings. New findings will be communicated to the data recipient.

Any finding identified during the onsite visit and corrected by the data recipient prior to the Audit Team leaving will be referenced in the audit report together with an acknowledgement that the issue was corrected.

The Audit Team may request pre-existing evidence that was unavailable at the onsite visit to be supplied within five working days of the visit, except where the Lead Auditor specifies a different timeframe during the closing meeting. The Audit Team will not review material generated or updated after the onsite visit; such material may be reviewed as part of a post audit review.

If any issues of a serious nature are identified during the onsite visit, then the Audit Team will raise its concerns with the data recipient and NHS Digital immediately.

2.10.3 After the onsite visit

The Audit Team will review any material supplied following the visit, and any new findings will be communicated to the data recipient and included in the draft audit report.

The Audit Team may seek advice from subject matter experts within NHS Digital following the onsite visit to address any unresolved issues.

2.11 Definition of findings

A finding will be classified according to one of the following designations:

- Agreement nonconformity
- Organisation nonconformity
- Observation

- Opportunity for improvement
- Follow-up

2.11.1 Agreement nonconformity

An agreement nonconformity is a failure to implement a requirement in a data sharing framework contract, data sharing agreement or communication between NHS Digital and the data recipient during or subsequent to the application.

An agreement nonconformity may also be raised against guidelines identified in the data sharing framework contract, including later versions, except when the data recipient is able to provide a documented justification as to why such guidance is not applicable.

2.11.2 Organisation nonconformity

An organisation nonconformity is a deviation from a requirement specified in the data recipient's own documentation.

2.11.3 Observation

An observation is a situation where a nonconformity had not arisen at the time of the audit but without appropriate action being taken a nonconformity could result. For example, the data recipient has identified members of staff that will process data supplied by NHS Digital shortly, but those staff have not completed the information governance training at the time of the audit. The observation would be that staff need to complete the training prior to processing data.

2.11.4 Opportunity for improvement

The Audit Team may identify opportunity for improvements (OFI) which could help an organisation improve its controls or their effectiveness based on the Audit Team's experience and knowledge from other data sharing audits.

2.11.5 Follow-up

Any material considered important by the Audit Team that could not be provided within the stipulated timeframe may be identified in the audit report as "follow-up". This material will be reviewed, by the Audit Team, at the post audit review. If issues are identified during the post audit review, further findings may be raised by the Audit Team.

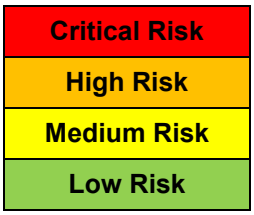
2.12 Risk Statement

The Audit Team will provide an overall risk statement in the audit report based upon the evidence presented during the audit and the type of data being shared at the time of the audit.

The risk statement will be based on:

- the nature of the data in terms of potential identification from those data items which could cause harm or distress
- the soundness of the data recipient's controls and their correct implementation
- the context in which the data is being used

The risk will be expressed as:



2.13 Headline findings to NHS Digital

A headline findings email will be issued to senior managers in NHS Digital by the Audit Team within the timescale stated in Table 2. The email will present the nonconformities, observations, opportunities for improvement, points for follow up and any other matters of interest which may be material to the audit.

2.14 Draft report

A draft audit report will be issued to the data recipient within the timescale stated in Table 2. The report will detail findings as described at the closing meeting and, if relevant, amended following the review of any documentation provided to the Audit Team after the onsite visit (section 2.10.3).

Although the Audit Team will consider all of the areas within the scope of the audit, the report is an exception report based on the compliance checks described in section 2.4. The audit report may also identify areas of good practice demonstrated by the data recipient.

The data recipient is requested to check the draft audit report for factual accuracy and for commercially confidential and security sensitive information. The data recipient should return its feedback and/or any suggested amendments to the Audit Team in accordance with the timescale shown in Table 2.

Should the data recipient not respond within the stated timescale, it will be deemed that the draft audit report has been accepted as factually accurate. If a data recipient requires additional time to consider its response, an extension request must be sent to the Lead Auditor (dsaudit@nhs.net) within the stated timeframe.

All factual inaccuracies will be corrected by the Audit Team. Other comments will be considered by the Audit Team on a case by case basis. Although rare, disagreement concerning the findings may occur between the two parties. Whilst it is a matter for the Audit Team to determine the content of the final report, where there is a non-resolvable disagreement a comment will be added to the report to reflect the data recipient's opinion. See also section 2.22.

The audit is based upon a sample of the data recipient's activities, as observed by the Audit Team. Therefore, the findings detailed in the audit report may not include all possible nonconformities which may exist.

2.15 NHS Digital Publication Meeting

Once any changes have been made to the draft report, following the receipt of comments from the data recipient, it will be taken to the next internal publication meeting. This meeting is attended by the Audit Team and representatives from DARS and Communications. The purpose of the meeting is to provide an opportunity for other specialist teams to offer advice and commentary on the draft audit report prior to its publication.

If any material changes to the report are suggested at the meeting and accepted by the Audit Team, then the Lead Auditor will discuss the changes with the data recipient prior to publication.

2.16 Final Report and Action Plan template

The Lead Auditor will email the final audit report to the data recipient and provide an indication of when the report is to be published online. If the final audit report contains nonconformities or items for follow-up, the email will state when a post audit review is expected to be performed, see section 2.21. The data recipient will also be requested to complete an action plan which address all the findings, see section 2.19.

2.17 Publication on Internet

The data sharing audit report will be published on the external NHS Digital website. Audit reports are scheduled to be published according to the timescales specified in Table 2. Circumstances that may restrict publication include purdah and public holidays.

The website for these reports is: https://digital.nhs.uk/services/data-access-request-service-dars/data-sharing-audits.

2.18 NHS Digital action resulting from an audit

Findings that present a serious divergence from the contract and agreement, or those findings which present an unacceptable risk to NHS Digital or to its stakeholders (including patients), will be addressed directly by DARS though its breach process.

A decision will be made by the NHS Digital Senior Information Risk Owner or Service Director for Data Dissemination on the course of action to take in response to any identified nonconformities.

2.19 Data recipient response to findings

The audit report may require a data recipient to provide an action plan which details the action to be taken, the name of the action owner and the target date for each action. It is the responsibility of the data recipient to decide on an appropriate course of action and ensure it addresses the findings.

In addressing a finding, the data recipient must take account of any referenced supplementary notes presented in the audit report. The data recipient may use its own action plan template, or the template provided in Appendix D. A Word version of this template can be found on the DARS audit SharePoint site; currently https://digital.nhs.uk/services/data-access-request-service-dars/data-sharing-audits.

The data recipient will send the annotated action plan to the Lead Auditor (dsaudit@nhs.net) no later than the timescale specified in Table 2. The Audit Team will review the action plan and check that the actions planned by the data recipient have the potential to address the findings and the timescales appear reasonable. The Lead Auditor will inform the data recipient of any concerns with respect to the proposed action plan.

2.20 Timescales

The timescales shown in Table 2 will be dependent upon the outcomes of the audit and are subject to change.

Action	Responsibility of NHS Digital	Responsibility of data recipient
Send out notification letter and draft audit plan	Minimum of 10 working days prior to proposed onsite visit	
Completed audit plan returned to the Lead Auditor		As defined in the notification letter, but a minimum of 5 working days prior to proposed onsite visit
Provision of data recipient's documentation		As defined in the notification letter, but a minimum of 5 working days prior to proposed onsite visit
Onsite visit	Agreed audit onsite visit date	
Headline findings to NHS Digital Senior Managers	Within 5 working days of the onsite visit	
Draft audit report issued to data recipient for comment	Within 10 working days following the onsite visit	
Any comments on the draft audit report returned to Lead Auditor		Within 10 working days of receipt of draft audit report
Internal publication meeting	The publication meeting is typically held first week of the month	
Final audit report produced and sent to the data recipient	At least 5 working days prior to the report being published on the NHS Digital website	
Final audit report published on NHS Digital website	Typically, the third week of the month	
Provide annotated action plan		Within 10 working days from issue of the final report to the data recipient

Table 2: Audit Timings

2.21 Post audit review

The Audit Team will assess the actions taken by the data recipient to address the findings presented in the published audit report as part of a post audit review. A post audit review may also be undertaken when the report identifies issues not covered during the audit.

A review of the data recipient's action plan and supporting evidence to demonstrate the actions addresses the findings and are effective will be undertaken by a member of the Audit Team.

The Audit Team will contact the data recipient to request an update on progress of the action plan. A post audit review will generally be conducted three to four months following publication of the audit report. However, the timing will depend on the criticality of any of the findings and any action taken by NHS Digital (see section 2.18). The actual timing of a post audit review will be communicated to the data recipient by the Lead Auditor with the final report.

The type of post audit review will be determined by the overall audit findings, the resulting actions and the nature of the evidence supporting the actions.

The review will comprise at least one of the following:

- independent desktop review of the evidence
- telephone / conference call to walk through the evidence
- video call so that evidence held on the data recipient's system can be presented
- further onsite visit.

The Audit Team will raise internally any serious concerns in relation to any nonconformities which have not been addressed or the corrective action taken itself represents a serious risk to NHS Digital, see section 2.18.

A draft post audit review report will be written following the review. The report will be produced in the same way as the original audit report and will detail progress taken to address the findings raised. The risk statement will be updated accordingly.

The process of publishing this report will be the same as the audit report.

2.22 Issues and concerns

If the data recipient has an issue or concern with any aspect of the audit process, then the issue should be raised directly with the Lead Auditor. Where the Lead Auditor cannot resolve the issue satisfactorily, or in a timely manner, then the data recipient may raise a formal complaint.

The NHS Digital complaints procedure can be found at: https://www.digital.nhs.uk/feedback-complaints

2.23 Providing feedback

Feedback received from data recipients is used to further improve our audit process to ensure it remains relevant and well managed. A data recipient will be sent a feedback questionnaire once the final data sharing audit report has been released.

Appendix A Examples of Evidence

This appendix describes the type of questions and typical evidence related to the area of scope considered on a data sharing audit, highlighted in section 2.4. The purpose of this appendix is to help the data recipient prepare for the audit and to identify suitable representatives to meet with the Audit Team.

Within the scope of the key objectives, the Audit Team is free to explore any aspect in detail to assure itself that appropriate controls are in place and that there is suitable evidence to demonstrate the controls are being followed and are effective.

The following tables provide examples of evidence the Audit Team may wish to view. It should be noted that other sources may be requested by the Audit Team to support the audit. Note that whilst similar evidence may be listed under more than one area, the data recipient will only be required to supply this once.

Information transfer	
Aim: Establish the flow of data supplied by NHS Digital and the infrastructure being used to process and store such data, identifying all data touchpoints	
Typical opening questions/requests	**Examples of evidence**
• Describe the data recipient's infrastructure and the interfacing to any relevant third parties. • How does data flow around the whole infrastructure and specifically where does data reside? • How long will data be resident and what processes are in place to review its retention? • Is data processing/storage in line with the data sharing framework contract or agreement? • Is there a suitable contractual relationship with any third-parties? • Are technical reviews carried out when platforms are changed?	• Information flow mapping • Storage and backup policies • Contract/agreements with any processors or third-party data centres involved in processing or storing data supplied by NHS Digital • Sub-licencing arrangements

Access control	
Aim: Establish the controls and security measures in place at the processing and storage locations to control access to the data	
Typical opening questions/requests	**Examples of evidence**
• What are the physical security measures in place within offices and data centre(s), where appropriate? • Is suitable access only available to recognised / approved users for each of the touch points identified under information transfer? • Is access amended in the event of personnel changing roles? • Is appropriate security testing, for example penetration testing and vulnerability assessments, undertaken by the data recipient? • Does the data recipient have policies, processes and procedures related to asset management patch management, configuration control in place? • How does the data recipient ensure any information passing over public networks is protected from fraudulent use, modification or disclosure?	• Information security policies and guidance • Account protection including organisational IT infrastructure, for example, firewalls, encryption, anti-virus / anti-malware and patching policies • User / customer access permissions • Authentication process including logging and monitoring • Hardware and mobile device user management • Hardware and software encryption • Joiners, leavers and movers processes • Change management process • Password policy and processes • Physical building access controls • Remote access policy • Guest access policy • Physical and environment controls around the storage of data (server rooms and data centre) • Security assessments, including vulnerability assessment and penetration tests reports

Data destruction	
Aim: Determine whether the data is adequately destroyed electronically or physically from all established touch points	
Typical opening questions/requests	**Examples of evidence**
• Is there an established framework for the destruction of data and the media on which data is recorded (paper and electronic)? • Does the data recipient maintain sufficiently detailed records for those items sent for destruction? • Are decommissioned assets held in a secure area until destroyed? • How are assets destroyed? • Is a suitable third party used to destroy assets? What records are produced by the third-party to demonstrate that the assets have been destroyed? • How is the destruction of an asset linked back to the equipment asset register? • Have Data Destruction Certificate(s) been returned to NHS Digital?	• Information asset register • Equipment asset register • Data disposals policy and processes • Contract / service level agreement with any third-party disposal company • Disposal log • Certificates of destruction from disposal company • Destruction of paper-based information records • Sub-licencing arrangements

Operational management and control	
Aim: Assess the data recipient's internal controls to ensure that data is handled appropriately and that these controls are known to relevant staff and have been independently validated	
Typical opening questions/requests	**Examples of evidence**
• How does the data recipient remain compliant with legal and contractual requirements? • What are the data recipient's information security and information governance assurance processes? • Who has responsibility to manage and control information governance processes? • How are new and updated policies/processes/procedures communicated to all staff? • Does the data recipient have an internal audit programme in place? • How does the data recipient identify and manage its information and equipment assets? • How does the data recipient manage and report incidents? • Does the data recipient have an established information governance training programme, which includes refresher training?	• Information Governance Framework • Information governance policies • Data Protection Impact Assessment • Evidence of Senior Management ownership of information governance • Minutes of meetings • Incident management processes and any associated tools • Information asset register • External and internal audit plans and audit reports, covering IT Security and Information Governance in the area in scope of the audit • Employee awareness and training policies, including information governance training materials and training records for both staff induction and refresher training • Sub licencing arrangements

Use and benefits of data	
Aim: Determine the data is being used for the agreed purpose and that suitable checks are made prior to any release / publication	
Typical opening questions/requests	**Examples of evidence**
• Is the data being used in accordance with the agreed purpose? • Are the declared benefits being achieved? • Has the data recipient recognised NHS Digital's copyright, when appropriate?	• Publications and research papers • Analytical software / tools • Sub-licencing arrangements • Operating procedures • Output register of deliverables / research papers

Risk management	
Aim: Ensure risks around the handling of the data have been identified, documented and, where necessary, mitigated	
Typical opening questions/requests	**Examples of evidence**
• Does the data recipient have a formal risk and issue management process? • Have IT, IG and project risks associated with the NHS Digital data assets been identified and recorded? • Does the data recipient have a declared risk appetite? • Have additional controls to unacceptable risks been identified and implemented? • Is there evidence to show that risks are periodically reviewed to ensure that controls remain relevant and effective?	• Risk management framework / procedure • Risk register(s) and associated controls • Risk assessments / mitigation • Minutes of management meetings • Risk assurance reports to Senior Management

Appendix B Representative NHS Digital Audit Plan

Data Recipient		Date of Audit	
Named Contact		NHS Digital Audit Team	
Location(s) of Audit			
Scope of Audit	Type of audit: [Routine / Focused / Pre-release / Heightened Concern] Data Sharing Framework Contract: [reference] Data Sharing Agreement(s): [reference(s)]		

Audit Plan	Focus	Names and role of attendees
[Date]		
9:00 – 9:30	Audit team preparation time	NHS Digital auditors only
9:30 – 9:40	Opening meeting	*Please list names and roles***
9:40 – 10:00	Background to organisation and data sharing agreement	*Please list names and roles***
10:00 – 12:45	Information transfer Access control	*Please list names and roles***
12:45 – 13:45	Auditor time and lunch	NHS Digital auditors only
13.45 – 14:45	Data destruction	*Please list names and roles***
14.45 – 16:15	Operational management and control	*Please list names and roles***
16:15 – 16:30	Auditor time	NHS Digital auditors only
16:30 – 16:45	Feedback on the day and any changes in the schedule for tomorrow	*Please list names and roles***
[Date]		
9:00 – 9:30	Audit team preparation time	NHS Digital auditors only
9:30 – 9:45	Receipt of any available evidence	As required
9:45 – 10:30	Use and benefits of data	*Please list names and roles***
10:30 – 11:15	Risk management	*Please list names and roles***
11:15 – 12:00	Where appropriate and time allows, we will visit the location where NHS Digital data is located / held.	*Please list names and roles***
12.00 – 13:00	Auditor time and lunch	NHS Digital auditors only
13:00 – 14.30	Outstanding issues Opportunity to provide evidence that was not available at the time of meeting.	As required
14:30 – 15:30	Auditor time	NHS Digital auditors only
15:30 – 16:15	Closing meeting	*Please list names and roles***

** To be populated by Auditee with list of names and roles for persons attending on behalf of the organisation to answer questions round the topics area. Expected attendance is between 1 and 3 people, except for opening and closing meetings.

Appendix C Documentation Checklist

This checklist indicates the type of controlled and uncontrolled documents which should be provided to the NHS Digital Audit Team prior to the onsite visit. Controlled documents could be strategies, policies, procedures, work instructions or guidelines. Uncontrolled documents may be lists or general organisation information.

The Audit Team requires those documents which cover the defined scope areas. Some documents may cover several areas, or several documents may relate to a specific aspect of the audit. The list is not exhaustive and any relevant controlled documents which are applicable to the data recipient and third-parties, involved in processing data, should be supplied.

The data recipient should identify in the righthand column which documents have been supplied against the referenced representative documents.

Organisation Background and Data Sharing Agreement: Key organisation aspects and people		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Organisational and governance structure • Key staff roles and responsibilities • Infrastructure of ICT and IG - in house or outsourced	Organisation organogram	
	Governance structure including key roles and responsibility	
	List of IAAs and IAOs for data assets supplied by NHS Digital	

Information Transfer: Assess all touch points for the data		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Information flow mapping • Information security • Storage and backup • Contract / agreements with data processors / third parties / sub-licencing	Data flow diagram	
	Data handling	
	Storage and backup	
	Contract / agreements with third-parties providing processing, storage and deletion services (if such contracts are deemed commercially sensitive, the Audit Team will review onsite)	

Access control: Review the access controls in place at the storage and processing locations		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Account protection • Physical and environmental controls • Access permissions • Joiners, leavers and movers • Password management and authentication process • Security assessments • IT system and access change management	Internet security	
	Network security	
	Data security including encryption	
	Mobile working management	
	IT patch management	
	Password management	
	Access management and control	
	User and administration account management	
	Anti-virus and malware	
	Logging and monitoring	
	Remote access	
	Use of removable media	
	Data storage	
	Penetration testing	
	Starters, leavers and movers	

Data destruction: Data destruction and hardware disposal for each touch point		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Data destruction - data destruction process on live system • Asset disposal - hardware disposal process	Information management	
	Data retention and disposal, including disposal of IT assets	
	Asset management	
	Asset registers	

Operational management and control: Review of IG controls e.g. owner, IAR, Incidents; training and audit, DPIA etc		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Training - basic training and specialist training (IAO, IAA and SIRO etc.) • Information asset register • Policies awareness - accessibility, control, review process, communication of updates, compliance check • Management and review of organisation's policies • Data Protection Impact Assessment (DPIA) - review and approval process • IG process covering information governance, information security, and data protection, code of conduct etc • DSPT - evidence leads, review process, independent audit • Incident management • Audit and compliance - audit reports, checks against contract, agreement and GDPR. Privacy statement and ICO registration	Data protection	
	Management and security of information assets & information systems	
	Information governance	
	Staff induction	
	Staff mandatory training including data protection training	
	Information handling	
	Information / data classification	
	Records management	
	Policy and procedure management	
	Confidentiality code of practice	
	Incident management	
	Acceptable use	

Use and benefits of data: Review outputs from the data and quality checks prior to use and publication		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Tangible outputs against the Data Sharing Agreement • Quality checks on outputs - copyright statement, small number suppression	Quality Policy	
	Quality committee terms of reference	
	Management of datasets	
	Review of deliverables	

Risk management: Review of approach to managing risks and issues		
Areas Covered	**Documents Addressing**	**Document(s) Provided**
• Risk management	Risk management	
	Risk assessment template form	

Appendix D Action Plan

The following table shows an action plan which a data recipient may use to record the actions proposed or taken to address the audit findings, see section 2.19. This table is available as an independent download from the NHS Digital website: https://digital.nhs.uk/services/data-access-request-service-dars/data-sharing-audits.

The three status assignments are:

- Open – the action is still being progressed
- Closed – the action has been suitably completed
- Rejected – the data recipient has chosen not to action an Opportunity for Improvement (OFI) raised by the Audit Team. A brief statement should be included under "Action Proposed / Taken" as to why the OFI was rejected

Ref	NHS Digital Finding	Designation	Action Proposed / Taken	Owner	Due Date	Status	
1.		Select			Select	Select	
2.		Select			Select	Select	
3.		Select			Select	Select	
4.		Select			Select	Select	
5.		Select			Select	Select	
6.		Select			Select	Select	
7.		Select			Select	Select	
8.		Select			Select	Select	
9.		Select			Select	Select	
10.		Select			Select	Select	

Appendix E Glossary

Term	Abb	Definition
Certificate of Destruction		A certificate signed by an authorised representative of the data recipient, or specialist third party engaged to securely destroy the data, and provided to NHS Digital within a defined timescale. The certificate assures NHS Digital that the data and all hard and soft copies thereof have been securely and permanently destroyed in accordance with applicable Law and guidance, including the NHS Digital Destruction and Disposal of Sensitive Data Good Practice Guidelines.
Controller		Defined in Article 4 of GDPR as “the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data”
Data		The health or social care data provided by NHS Digital to the data recipient under a data sharing agreement
Data Access Officer	DAO	Member of NHS Digital staff responsible for a data sharing agreement
Data Access Request Service	DARS	Department within NHS Digital responsible for data sharing framework contracts, data sharing agreements and the dissemination of data
Data Protection Act	DPA	The Data Protection Act 2018 makes provision for the regulation of the processing of information relating to individuals and supplements the EU GDPR
Data Protection Impact Assessment	DPIA	A process designed to help identify and minimise the data protection risks of a project
Data Recipient		The party named in Clause 1.2 of Part 1 of the data sharing framework contract who will be a Controller of any personal data to be shared in accordance with the contract and any data sharing agreement. Within this guide, the term also includes third-parties such as a processor, sub-licensee, contractor or otherwise.
Data Security and Protection Toolkit	DSPT	An online self-assessment tool that enables organisations to measure and publish their performance against the National Data Guardian's ten data security standards. All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance they are practising good data security and that personal information is handled correctly.
General Data Protection Regulation	GDPR	The European Union General Data Protection Regulation, namely Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data
Guidance		Any applicable guidance or standards including codes of practice, standards and guidance issued by the Information Commissioner, the Department for Health, NHS England, the Standardisation Committee for Care Information and NHS Digital, including by way of example but not limited to those identified in Schedule 3 of the data sharing framework contract

Information Asset Administrator	IAA	Supports the IAO in fulfilling their duties, for example, ensure that policies and procedures are followed, recognise actual or potential security incidents, consult with the IAO on incident management and ensure that information asset registers are accurate and up to date
Information Asset Owner	IAO	A senior member of staff who is the nominated owner for one or more identified information assets within the data recipient
Information Asset Register	IAR	A list of personal and non-personal information assets held by the data recipient
Information Commissioner's Office	ICO	The UK's independent body set up to uphold information rights
Information Governance	IG	Information governance is the management of information at an organisation. Information governance balances the use and security of information. Information governance helps with legal compliance and operational transparency.
Lead Auditor		The person responsible for the management of a data sharing audit on behalf of NHS Digital
Personal data		Defined in Article 4 of GDPR as "any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person"
Processing		Defined in Article 4 of GDPR as "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction"
Processor		Defined in Article 4 of GDPR as "a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller"
Pseudonymisation		Defined in Article 4 of GDPR as "the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person"
Senior Information Risk Owner	SIRO	Executive Director or member of the Senior Management Board of an organisation with overall responsibility for an organisation's information risk policy.
Special Condition		The special conditions for processing the data as set out in the relevant data sharing agreement
Sub-Licence		A written agreement entered into between the data recipient and a sublicensee as referred to in clause 3.2.3 of Part 2 of the data sharing agreement