



Barts Health
NHS Trust

NHS Research Records: Reducing Risk

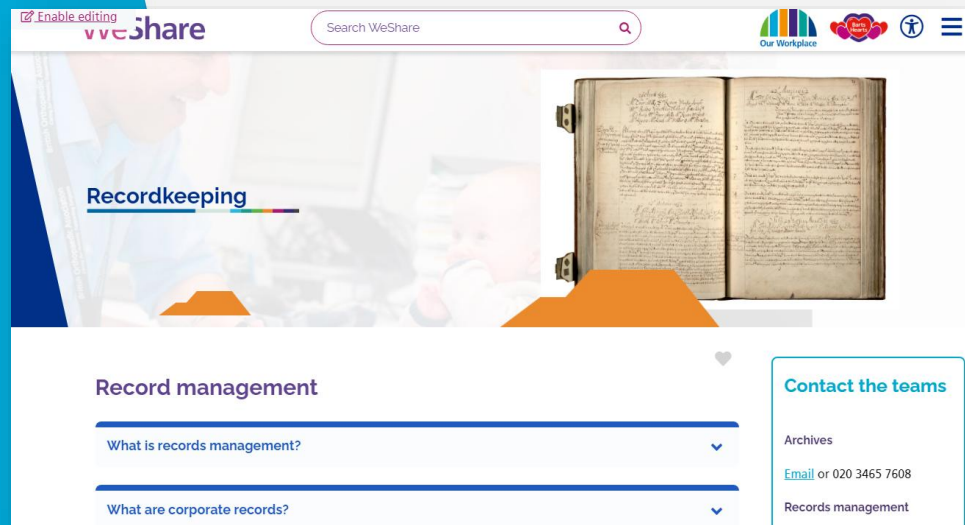
Sandra Blake & Emma-Louise Day

11th March 2025



Corporate Records service

- Traditionally stored paper records only
- Post-2020 increase in born digital material
- Until 2023, we had no approved digital archive



The screenshot displays the vveShare website interface. At the top, there is a navigation bar with the 'enable editing vveShare' logo on the left, a search bar labeled 'Search WeShare' in the center, and several icons on the right including 'Our Workplace', a 'vveShare' logo, and social media icons for Facebook and a menu. Below the navigation bar is a hero section with a background image of a man and a baby, and an open book. The word 'Recordkeeping' is overlaid on the image. Below the hero section is a 'Record management' section with a heart icon. Underneath this section are two expandable items: 'What is records management?' and 'What are corporate records?'. To the right of the 'Record management' section is a 'Contact the teams' sidebar containing the text 'Archives', 'Email or 020 3465 7608', and 'Records management'.

New issues for 2020-2023

- Only provided a partial service
- Teams advised to print or store records elsewhere
- USBs and CDs/DVDs put in with paper records



8 RESEARCH STUDIES

See the [clinical trial regulations](#) for more information on the retention of records

	Record type	Retention start	Retention period	Action at end of retention period	Notes
8.1	Research falling under remit of the Medicines & Healthcare products Regulatory Agency (MHRA) or international equivalent	End of study	C+25 years	Review and consider Transfer to Trust Archives	All documentation, in any format, of any type, from any departments, including but not limited to: sponsor files, contracts, financial records, trial master file, site file, pharmacy site file, laboratory files, laboratory accreditation, lab books, source data, standard operating procedures and personal training records. This includes relevant, study-specific records administered by the Joint Research Management Office (JRMO). https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
37					
8.2	Advanced therapy medicinal products (as defined by MHRA)	Expiry date of the product	C+30 years	Review and consider Transfer to Trust Archives	All documentation, in any format, of any type, from any departments, including but not limited to: sponsor files, contracts, financial records, trial master file, site file, pharmacy site file, laboratory files, laboratory accreditation, lab books, source data, standard operating procedures, personal training records and product specification file. This includes relevant, study-specific records administered by the Joint Research Management Office (JRMO). https://ec.europa.eu/health/sites/health/files/files/eudralex/vol



Risks of not accepting digital records

Loss and corruption (inaccessibility) due to:

- Being printed (so not kept in original form)
- Being stored elsewhere (e.g. with the Sponsor)
- Being put into the boxes of paper records (e.g. USB sticks and CDs) - they will deteriorate on the shelf.
- Being stored on external media with short lifespans without a back-up regime in place.
- Not being able to actively manage and preserve records as technology advances over 25 years.





Risks of not accepting digital records continued

- Inappropriate access
- No easy way of knowing who has had access (no audit trails)
- Loss and theft of confidential data
- Unable to meet research quality standards (QMS/CSV/GxP)
- Data is siloed, and resources not consolidated.



**UK Research
and Innovation**

Archiving research documentation

It is important to preserve research data in the longer-term for a number of reasons:

- to support open science and promote reproducibility (important for transparency)
- to provide an audit trail or an archive of the research run in your organisation
- to enable future research opportunities through data or sample sharing

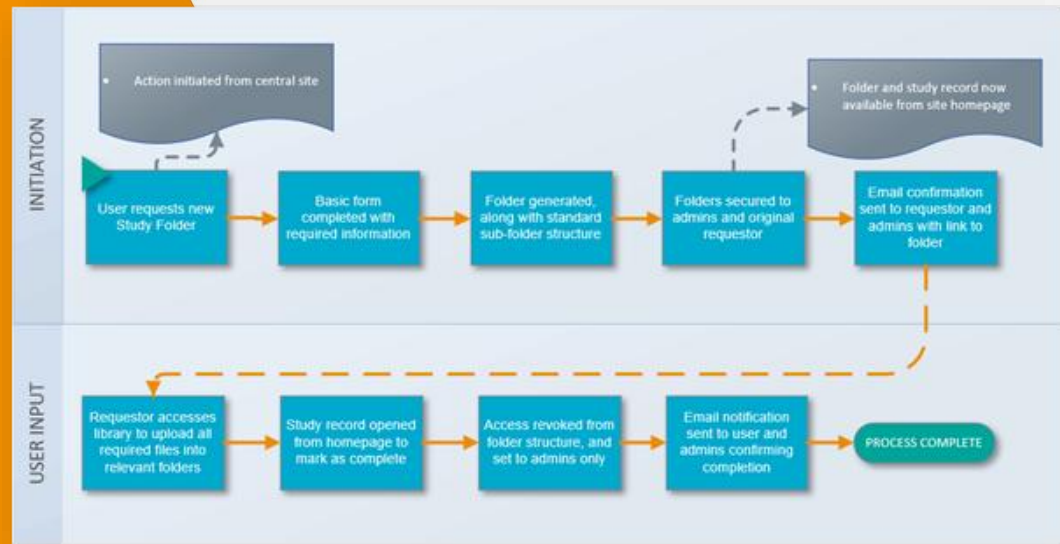
Clinical trials of investigational medicinal products (CTIMPs) must be archived in line with the clinical trials regulations. Learn more on [archiving in the Clinical Trials Toolkit](#).

The MRC Regulatory Support Centre [retention framework](#) can be used to inform decision-making about the retention of research data and related material.



A temporary solution

- Situation became more urgent
- Bespoke SharePoint site created with PowerApp
- Reduced the pressure on research staff
- Mitigated some of the risks but not all








Closed research studies

[Home](#) [Recycle bin](#) [Edit](#)★ Following [Site](#)[+ New](#) [Page details](#) [Analytics](#)Published 05/02/2024 [Share](#) [Edit](#)

My folders

[+ New](#) [Upload](#) [Edit in grid view](#) [Sync](#) [Export to Excel](#) [My folders](#) [Info](#)

 Name	Created	Modified
 2020-FORCE-IRAS246654	July 11, 2022	July 11, 2022
 2019-BAMI-IRAS109026	October 2, 2023	November 13, 2023

[+ Request a new Study Folder](#)[Request access to a pre-existing folder](#)[Contact a member of the team](#)

Business case for a specialist digital archive solution

- High-scoring risk logged on Trust risk register
- Feasibility proposal linked to risk

Current Risk Grading:

Use the table below to calculate the risk grading with **the current controls** in place.

		Consequence				
		1	2	3	4	5
Likelihood	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5
RISK SCORE		Risk Score: 16 - - Likelihood: 4 Consequence: 4 (H4x4)				

Feasibility Proposal for 2022/23

Investment Name	Digital archive solution for preservation of records		
Site/CSS/Corporate	Corporate	Date:	08/03/2022
Investment Type	Other: REV ICT software/systems	Version	1
Risk Rating	16	Risk ref	6867

Outcome

Report from the Investment Steering Committee 21/06/22



Business Case Name	GSS Corp Dev Digital archive solution for preservation of records
Business Case Reference	FP1043
Discussed at ISC RP	01/04/22, 10/6/22
Latest meeting considered	ISC 21/6/22
Capital Costs	Nil
Revenue Costs	
Risk ref	Risk ref 6867; Risk score 16
ISC proposal	ISC approve this proposal to be supported by GEB as the Service have confirmed that the additional revenue funds will be covered as follows: <ul style="list-style-type: none">- Non-recurrent set-up element from GSS accruals- Recurrent element from R&D health records recharges
Next steps	The service can now proceed with procuring the digital software solution

An approved digital archive solution 2023 - present



Industries ▾

Solution ▾

Case Studies

Resources ▾

Company ▾



Contact us



Introducing Arkivum's Digital Archiving Solution

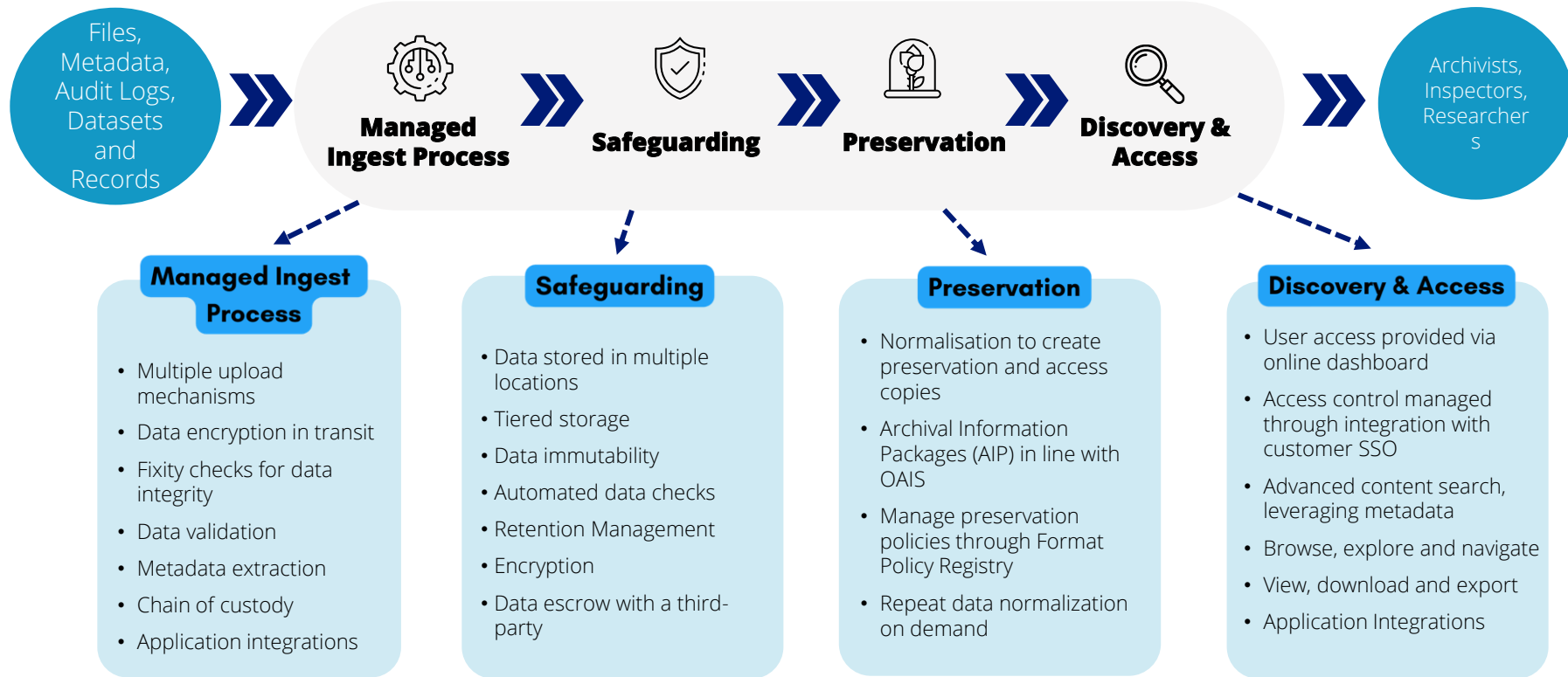
The Arkivum solution supports organisations with long-term data retention and archiving requirements.

Our solution provides the certainty for customers that their valuable digital content is searchable, accessible, and usable, forever. More than just data storage or archival, our data preservation system has been built to align with industry best practice approaches such as ALCOA++ and FAIR.

Customers have plenty of choices when uploading data into the Arkivum system. Options include drag and drop, upload from a cloud location, and integration with file-sharing systems such as SharePoint and OneDrive. For customers who require additional support, we also offer an optional data migration service.

The solution is also supported by a strict adherence to Quality Management processes and **Arkivum is certified in both ISO 9001 and 27001.**

Arkivum FAIR and GxP Data Archiving and Digital Preservation Solution



Cloud hosted SaaS, deployed on AWS with optional Data Escrow using Azure.
Fixed and known locations for data processing and storage, including US, EU or UK



Utilising the system at Barts

To date, we have now:

- Ingested all closed research studies that have been sent to us
- Become one of the first (if not the first) trust to set bespoke fees for commercial sponsors to store their digital records
- Engaged with corporate services to start ingesting other record types with long retention periods



The screenshot shows the Arkivum web interface. On the left is a navigation sidebar with options: Dashboard, Admin, Explore, PCDM Explorer, File Explorer, Reports, Ingest, and Notifications. The main area displays a file tree structure under 'Home' with folders like 'P_C_2020-REAL5-IRAS261133/' and 'Trial Master Files'. A table of documents is shown on the right with columns for Name, Modified Date, and ID. The table contains several rows of document entries, each with a PDF icon and a circular status icon.

Name	Modified Date	ID
P_C_2020-REAL5-IRAS261133/ ...		37890117-cac6-4232-96a9-0a211e4366ac-4263-uk-central-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/37890117-cac6-4
DIP_C_C_2020-REAL5-IRAS261133/ ...		d819a045-3b25-4aeb-bd4c-9725f266972e-REAL4_Sompaci-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/d819a045-3b25-
AIP_C_C_2020-REAL5-IRAS261133/_reduced ...		fbd34ab0-9ecc-48d7-9aab-22dc9058fa31-4263-uk-centra-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/fbd34ab0-9ecc-
AIP_C_C_2020-REAL5-IRAS261133/_complete ...		c3ca51eb-4dc8-4a9e-898d-a87d2cbd16ef-4263-uk-centra-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/c3ca51eb-4dc8-
C_2020-REAL5-IRAS261133/ ...		dfe59c7-14fb-4c71-8102-47b90ef44b58-4263-uk-central-i-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/dfe59c7-14fb-4
O_2020-REAL5-IRAS261133/ ...		80ab8e76-187a-49bd-b8b1-5bd689596ed8-4263-uk-Shipp-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/80ab8e76-187a-
2020-REAL5-IRAS261133 ...		69a54732-15a3-4107-85f1-abb3f51fe642-GB_632_System-f-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/69a54732-15a3-
Trial Master Files ...		cbd25d96-ae4a-4c36-bcf4-eb84cbd831b5-4263-GB-site-f-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/cbd25d96-ae4a-
Study-related training ...		492e5b2c-0b1f-4ed1-a99a-2689124ecffa-4263-uk-central-I-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/492e5b2c-0b1f-4
Site Files ...		e8b073c4-9a99-4426-9268-5db93a3b51d0-4263-parxel-f-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/e8b073c4-9a99-
Safety Reports ...		95251302-69f8-4a68-b406-5ba0e4431ceac-4263-uk-iec-me-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/95251302-69f8-4
Study protocol and amendments ...		84bfb754-33e4-497d-b506-301e5fbac6d6-4263-uk-central-IRAS261133/67af4b9f43e7b0879c70e0e/dip/objects/84bfb754-33e4-
Manuals ...		4e727c57-b017-4984-ab0c-1d9cf5781386-01_Apr_2022-30_
Investigator Site Files ...		
Investigator Brochure ...		
Administrative Information ...		





ID	Years	Days	Hours	Minutes	End Date	Is Default	Type	Reason	Action
Action_01/2045					2045-01-01 00:00:00	false			Review
Action_01/2049					2049-01-01 00:00:00	false			Review
Action_01/2048					2048-01-01 00:00:00	false			Review
Action_01/2050					2050-01-01 00:00:00	false			Review
Action_01/2046					2046-01-01 00:00:00	false			Review



Navigation

- Dashboard
- Admin
- Explore
- Reports**
- Audit Trail**
 - Ingest
 - Preservation
 - Normalisation
 - AtoM DIP Upload
 - Hold
 - Unhold
 - Reparenting
 - Export
 - Deletion
 - Ingest
- Notifications



User ID	Event Type ...	Event	ID	Job ID	Action	Reason	Time Stamp...
emma-louise.day...	AUTHENTICATION_L...	Login	emma-louise.day...		User logged in		2025-03-07 14:57:53
emma-louise.day...	AUTHENTICATION_L...	Login	emma-louise.day...		User logged in		2025-03-07 14:17:41
emma-louise.day...	AUTHENTICATION_L...	Login	emma-louise.day...		User logged in		2025-03-05 16:31:45
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	P_C_2020-REAL5-L...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:46:39
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	/IRAS261133/67af4b...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:43:49
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	/IRAS261133/67af4b...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:43:49
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	/IRAS261133/67af4b...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:43:49
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	/IRAS261133/67af4b...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:43:49
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	/IRAS261133/67af4b...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:43:49
emma-louise.day...	AGGREGATION_RET...	Retention Schedule Inheri...	/IRAS261133/67af4b...	67af5638143e7b08...	Retention inherita...		2025-02-14 14:43:49



Expanding the service 2025

- Expansion of service to other NHS organisations now fully set up and ready
- Engaging with potential customers and Arkivum to gauge requirements and best model (direct procurement or through Barts as a reseller)
- Winning the award generated more interest
- Displaying a poster at RDF25 (NHS Research & Development Forum conference) in May to advertise



(1) BARTS HEALTH NHS TRUST

- and -

(2) **[INSERT NAME OF OTHER PARTY]**

**Service Agreement
for the provision of
Digital Records Storage**



Thank you.



For questions or more information:

records.management@nhs.net

