



SUSQI PROJECT REPORT

Reducing the Research Footprint: A Sustainable Quality Improvement Evaluation of Electronic Investigator Site Files

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Background:

Hampshire Hospitals NHS Foundation Trust (HHFT) continues to embed research at the heart of patient care, with 3,264 participants recruited in the last financial year (2025-2026) into more than 65 studies spanning over 20 clinical specialties, including cancer care, reproductive health and childbirth and Trauma and Emergency care. Over half (55%) of these studies are trialling innovative new drugs or medical devices, ensuring patients have access to cutting-edge treatments while driving improvements in outcomes and service delivery across the Trust. In addition to studies currently recruiting participants, the research department supports the continuing follow-up of many long-term research projects. Clinical research activity not only enables participants to access treatment options not available to them through standard care but also improves the outcomes of all patients within the organisation. (Osdemir BA, et al. 2015.)

The research and development (R&D) department (38 whole time equivalents posts) comprises several teams. A governance team who ensures compliance with all research and trust regulations, manage research approvals, contracts and governance of all research activity at the Trust. The trust also has three general clinical research delivery teams (a mixture of registered and non-registered staff), who support the set-up and all aspects of research delivery and care of research participants. Research across the trust is also supported by several peripatetic specialist research delivery teams - peritoneal malignancy, orthopaedics and hepatobiliary surgery. All research delivery depends on collaboration with clinical teams - both those who act as Principal Investigators (the study lead on site) and all those who support the delivery in their areas. Our green team is comprised of representatives from both governance and delivery teams who collectively have more than 30 years experiences in research.

Research has traditionally been a speciality that generates a lot of paper, as you can see from the amount of lever arch files in figure 1. One important requirement of a research site conducting clinical

trials of new medicines and devices is that we maintain an Investigator Site File (ISF). This contains all the relevant records and can be multiple files per study. This ISF must be maintained throughout the study lifetime and archived for up to 25 years after the study completion. These archived records are prepared and then stored offsite at the Trust facility (RESTORE). The records can be inspected at any time by the sponsor, or during a regulatory inspection by e.g. the MHRA, therefore it is important, much like clinical documentation of care, that they are constantly updated, and available.

In a Trust that has been leading the way in paper lite and digitised care for more than 20 years, it seems incongruent that HHFT Research currently operates without a compliant electronic system for managing and archiving ISFs, research documentation and training records. Instead, processes rely on paper-based files and multiple unintegrated systems, including local drives and the Trust's Quality Management System for standard operating procedures (SOPs). This fragmented model impacts all research delivery areas, including research governance, study set-up, clinical research teams, and support services (e.g. pharmacy and radiology), creating duplication, inefficiencies, and inconsistent oversight. Research practice is governed by multiple sources of regulation, including HHFT policies, the UK Research Governance Framework, the MHRA, and International Committee on Harmonisation – Good Clinical Practice (ICH-GCP). The latter is a gold-standard global certification undertaken by all those involved in research and is aimed at ensuring the safety and well-being of research participants, and the integrity (accuracy, traceability) of the data collected. Many governance requirements are derived from this standard (HHFT Policy 2024; Health Research Authority, 2017; ICH, 2016; Medicines and Healthcare products Regulatory Agency, 2020).

It has been identified that the current mixed and mostly paper-based approach presents a clear and increasing risk to regulatory compliance with ICH GCP and MHRA expectations, particularly in relation to document control, audit trails, and inspection readiness. It also limits the Trust's ability to support remote monitoring, which is now standard practice across commercial and complex studies, and reduces overall research capacity due to the administrative burden placed on staff. (Health Research Authority, 2017; ICH, 2016; Medicines and Healthcare products Regulatory Agency, 2020).

Considering these research-specific priorities in the context of the Trust's organisational vision, addressing the problem above would have an impact in all the Trust's strategic areas:

- Providing outstanding care for every patient
- Making our trust a great place to work
- Working together for our population
- Making the best use of our resources
- Innovating for a sustainable future

Moreover, the Trust's Green plan outlines four areas of opportunities to embed sustainability into our practice and organisation: Reducing Waste, Embedding Action, Lower Carbon Alternatives and Lean pathways, stating that 'the biggest challenge to public health this century is climate change'. Change is required across all services to meet this challenge. Our project is focussed on the low carbon and lean service delivery principles of sustainability (CSH).

Examining the possible alternatives to the traditional paper-based methods of maintaining an Investigator Site File can help us meet both our regulatory requirements, and contribute to the Trust's

sustainability vision. An opportunity to investigate this further presented itself when a study sponsor working with the organisation, revealed they were using an electronic trial master file/investigator site file system. Some of the R&D department were familiar with the concept, but this gave us an opportunity to trial it and determine how this might work in practice. The more we worked with this, the more we saw opportunities to streamline our operations, remove duplication, and become more efficient with our time and resources. Contributing to meeting the Trust's net zero goals would however lead to the most important endpoint of all – being able to offer more people the opportunity of taking part in research.

Specific Aims

To evaluate the environmental, financial and social impact of replacing paper-based Investigator Site File (ISF) management and archiving processes with the Florence Healthcare electronic Investigator Site File (eISF) platform at HHFT. The project aimed to determine whether digital archiving could reduce carbon emissions, operational costs and staff administrative burden whilst maintaining regulatory compliance and research governance standards.

Methods

To understand the current state, a review of existing research document management processes was undertaken across the R&D Department, including research governance, study set-up and research delivery teams. The project team mapped the end-to-end lifecycle of a typical study file from study set-up, through active use, monitoring and long-term archiving.

A data collection tool was developed to quantify the activities, costs and environmental impacts associated with both the current paper-based pathway and the proposed Florence pathway. Data was gathered from:

- Internal process mapping and staff experience.
- A dedicated staff survey exploring current processes and perceptions regarding digital archiving.
- Restore Records Management archive pricing schedules.
- Florence Healthcare pricing proposals and implementation documentation.
- Manufacturer specifications for folder maintenance and printing-related consumables.
- NHS energy and transport assumptions.

The project team also reviewed national guidance, including the National Contract Value Review (NCVR) process and existing commercial costing arrangements to determine whether costs associated with electronic archiving could reasonably be recovered through commercial study pass-through charges, alongside national policies such as the NHS 10 Year Plan, which clearly outline the strategic need for the NHS to move away from analogue 'paper' processes towards digital solutions.

Process mapping:

A process mapping exercise was undertaken to understand the current lifecycle of research documentation and identify activities contributing to environmental impact, staff burden and financial cost.

The process map (figure 2) was developed through discussions with research governance staff, research delivery teams and support services involved in study set-up, document management and archiving. The exercise mapped the complete lifecycle of a typical ISF from study initiation through to final archiving and destruction.

The process map was subsequently used to identify potential environmental, financial and social impacts associated with paper-based processes and to compare these with the proposed Florence Healthcare electronic pathway. The mapping process identified multiple manual activities, including:

- Printing and filing study documentation.
- Obtaining wet signatures.
- Preparing files for archive and retrieval of archived records when required.
- Manual handling of archive boxes and transport of records to off-site storage.
- Final confidential destruction.

Reducing the Research Footprint: Process Map (Figure 2)



Figure 2 – R&D Process Map

Key Data Assumptions Used

As exact activity data was not available for every study, several assumptions identified during process mapping were applied to create a representative model.

A typical study was assumed to generate:

- Four lever arch files.
- Approximately 1,900 pages.
- One archive box weighing approximately 12kg.

The current pathway, represents managing 100 studies over 1 year, and included:

- Paper.
- Toner.
- Lever arch files.
- Archive boxes.
- Staff time to prepare studies for archive
- Archive storage.
- Environmental controls within archive facilities.
- Archive transport and retrieval.
- Staff time to retrieve and review studies coming back from archive.
- Shredding and destruction via confidential waste pathway.
- Staff time for destruction.

The Florence pathway, represents managing 100 studies over 1 year, and included:

- Florence licence and support costs.
- Implementation and training staff time.
- Digital trial management staff time.
- System administration.
- Remote monitoring of studies and associated staff time associated.
- User access through existing Trust computers.
- Long-term electronic preservation.

No additional hardware purchases were assumed because Florence can be accessed using existing Trust devices. A commercial contribution of £1,000 per commercially sponsored study towards electronic archiving costs was required.

Stakeholder Engagement

A wide range of stakeholders were engaged throughout the project to ensure that environmental, governance, technical, operational and financial considerations were appropriately assessed.

Internal Stakeholders

Research & Development Team HHFT

Engagement included R&D governance, delivery and support staff, alongside specialist research teams, study coordinators, administrative staff and senior R&D leaders.

A staff survey was circulated to all R&D teams to understand current challenges associated with paper-based ISFs, archiving processes, document retrieval, wet signatures, storage capacity and environmental sustainability. The survey also explored perceptions of Florence Healthcare, anticipated benefits and concerns relating to implementation. Survey findings informed both the social sustainability and process redesign elements of the project.

Information Technology (IT) - Digital Team HHFT

The Trust IT team were engaged to assess technical compatibility, infrastructure requirements, access arrangements and alignment with existing digital systems. Discussions focused on system integration, user access and ongoing technical support requirements.

Cyber Security and Digital Risk Teams HHFT

The Cyber Security and Digital Risk teams were consulted to understand information security requirements; cyber risk implications and system assurance considerations associated with adopting a cloud-based research management platform.

Information Governance (IG) HHFT

Information Governance colleagues were engaged to review data protection considerations, records management requirements, retention obligations and compliance with NHS information governance standards.

Project Management Office (PMO) HHFT

The PMO provided advice regarding project governance, implementation approaches, business case development and benefits realisation planning.

Procurement Team HHFT

Procurement engagement supported review of supplier pricing, contractual arrangements, implementation costs and potential routes to contract award.

Sustainability Team HHFT

The Sustainability team provided advice on the types of sustainability challenges our current processes present and how the digital solution might remedy these. They provided figures and data to support the NHS energy and waste systems that are outside of the control of R&D, for example confidential waste management systems and associated costs.

External Stakeholders

Florence Healthcare

Engagement was undertaken with Florence Healthcare representatives to understand system functionality, implementation requirements, electronic archiving capabilities, data storage arrangements, support models and pricing structures. Information obtained from Florence was used to develop the financial modelling and implementation assumptions used within this project.

Other NHS Trusts

Informal discussions were undertaken with staff at NHS organisations that have already implemented or are considering electronic ISF solutions including University Hospitals Southampton NHS Trust, University Hospitals Leicester NHS Trust and University Hospital Dorset NHS Trust. These discussions helped identify implementation considerations, anticipated benefits, lessons learned and examples of good practice.

Regional and National Research Networks

The proposal was discussed through research management and governance networks, including R&D Forum groups and professional networks. These discussions helped benchmark current practices, understand emerging national approaches to digital archiving and explore opportunities for wider adoption across the NHS.

Stakeholder Contribution to Project Development

Stakeholder engagement informed process mapping, impact assessment, modelling assumptions, implementation planning, risk assessment, staff readiness and consideration of wider NHS applicability.

Costs were also modelled based on review of current commercial research study costing practices as described by National Contract Value Review Tariff (NCVR).

Measurement

This project used the Centre for Sustainable Healthcare Sustainable Value framework (CSH 2026) to evaluate environmental, financial and social sustainability impacts associated with replacing paper-based ISFs with Florence Healthcare eISFs. Measurements were based on modelling the management and archiving of 100 research studies over a one-year period using current HHFT research activity assumptions.

Patient Outcomes Measurements

This project does not alter patient treatment pathways, clinical interventions, eligibility for research, or access to clinical services. No direct patient outcome measures are therefore anticipated.

The project aims to maintain the same standards of:

- Research governance
- Regulatory compliance
- Inspection readiness
- Participant safety oversight
- Data quality

while reducing environmental impact, financial cost and administrative burden.

Environmental Sustainability Measurements

A cradle-to-grave hybrid approach carbon footprint analysis was used to estimate the items greenhouse gas (GHG) emissions. Both paper-based and digital pathways were carbon footprinted using a process-based carbon footprint analysis. Items were weighed by the team and materials identified for the paper-based pathway.

Data was obtained from previous studies by the Centre for Sustainable Healthcare and other references. Where data was not available, calculations were made based on the weight and material of the product. Material weights were converted into GHG emissions using emission conversion factors taken from the Department of Energy Security and Net Zero (DESNZ)'s Greenhouse Gas Reporting Conversion Factors 2026 database, ICE V4.0 database and [Climatig](#). The analysis included GHG emissions associated with primary materials production, transport, and disposal.

Transport

Transport emissions per journey were calculated by weight of product, distance travelled and emissions per tonne.km travelled.

*Total emissions = Weight in tonnes per delivery*distance in km*emission factor*

The emission factor for diesel Class I vans (up to 1.3t) is 0.879 kgCO₂e per tonne.km.

Energy

Energy emissions were calculated by amount of energy used (kWh) and the UK emission factor of average emissions per kWh generated.

*Total emissions = amount of kWh used * electricity emission factor*

The 2026 UK emission factor for electricity including transmission and distribution is 0.1440 kgCO₂e per kWh.

Materials

Material emissions were calculated by the weight of the material, emission factor of the material and number of items.

*Total emissions = weight of material * material emission factor*

Functional unit

This project covers storage of data and materials associated with 100 research studies over a 1-year period. Tables 1 and 2 outline resources and activities measured for both the paper-based and Florence pathways.

Table 1. Resources and activities measured for paper-based pathway

Environmental Measure	Activity Measured
Paper consumption	Number of sheets of paper used in a standard research study
Paper purchasing	Number of reams of paper purchased.
Toner consumption	Number of toner cartridges required.
Lever arch file usage	Number of folders used per study.
Plastic wallet, labels and divider usage	Number of dividers, wallets and labels consumed.
Pen usage	Number of pens required.
Filing cabinet use	Physical storage furniture required.
Printing electricity	Electricity required to print study documentation.
Archive transport	Number and distance of archive transport journeys.
Archive retrieval journeys	Number and distance of archive retrieval requests.
Archive destruction transport	Number and distance of destruction journeys.
Archive storage	Number of archive boxes requiring long-term storage.
Archive facility energy	Lighting, temperature control, humidity control and security energy associated with archive storage.
Confidential waste	Quantity of confidential paper waste requiring destruction.
Courier and postage	Number of postal and courier movements associated with study documentation.

Florence Pathway - Environmental Sustainability

We measured:

Table 2. Resources and activities measured for the Florence pathway.

Environmental Measure	Activity Measured
Digital storage	Gigabytes (GB) of electronic storage required per study.
Backup storage	Additional storage required for backup and resilience.
Disaster recovery storage	Replicated storage requirements.
User access electricity	Electricity used by staff accessing Florence through existing Trust computers.
Data transfer	Data uploaded, downloaded and transferred through the system.
Data centre activity	Estimated data centre storage and processing requirements.
User authentication activity	Secure access and governance infrastructure supporting the platform.

Economic Sustainability Measurements

Financial measurements were derived from procurement data, supplier quotations, Florence Healthcare pricing information, Restore Records Management pricing schedules, NHS salary assumptions and commercial research study costing tariff information. Tables 3 and 4 outline the financial measures and activities assessed for the paper-based and Florence Healthcare pathways.

Table 3. Financial measures and activities assessed for the current paper-based Pathway

Financial Measure	Activity Measured
Paper costs	Cost of paper purchased.
Toner costs	Cost of toner cartridges.
Lever arch file costs	Cost of physical folders.
Divider and plastic wallet costs	Cost of supporting stationery.
Pen costs	Cost of stationery.
Filing cabinet costs	Cost of physical storage furniture.
Printing electricity costs	Electricity associated with printing.
Archive storage charges	Annual archive storage costs.
Archive transportation costs	Transport of files to archive.
Archive retrieval costs	Cost of archive retrieval.
Archive destruction costs	Costs associated with secure destruction.
Courier and postage costs	Postal and courier expenditure.
Staff time printing and filing	Staff costs associated with paper record management.
Staff time preparing studies for archive	Staff costs associated with archive preparation.
Staff time reviewing returned archive records	Staff costs associated with retrieval and destruction processes.

Table 4. Financial measures and activities assessed for the Florence Healthcare pathway

Financial Measure	Activity Measured
Florence licence costs	Annual platform costs.
Florence implementation costs	One-off implementation and configuration costs.

Staff implementation time	Internal resources required for deployment.
Staff training costs	Training and onboarding costs.
Staff time using Florence	Ongoing staff resource to manage electronic files.
Helpdesk and system administration	Internal support requirements.
User access electricity	Cost of electricity associated with system access.
Commercial sponsor contributions	Potential cost recovery through commercial studies.

Organisational Financial Outcomes

The following outcomes were compared:

- Total annual cost of paper archiving.
- Total annual cost of Florence Healthcare.
- Cost difference between current paper pathway versus implementing electronic ISF pathway.
- Estimated cost difference over 5 years.

Social Sustainability Measurements

Social sustainability measurements were informed by the staff survey, process mapping exercise and operational impact assessment. Tables 5-8 summarise the measurements undertaken to identify social sustainability. Nineteen responses were received from staff across R&D functions.

Table 5. Staff time and efficiency

Social Measure	Activity Measured
Time obtaining signatures	Staff estimates of effort required to obtain wet signatures.
Time preparing studies for archiving	Staff estimates of archive preparation activity.
Time printing and filing	Time associated with maintaining paper records.
Time retrieving archived records	Administrative burden of archive retrieval.
Time reviewing returned archive boxes	Activity required during destruction processes.
Time preparing for monitoring visits	Document preparation and room booking activities.
Time supporting monitoring visits	Administrative support for monitors (sponsor representatives who verify study procedures and data integrity).
Time managing study records	Ongoing file maintenance activities.

Table 6. Workforce experience

Social Measure	Activity Measured
Importance of environmental sustainability	Staff survey score.
Desire for greater sustainability focus	Staff survey score.
Storage pressure	Staff survey score.
Support for digital archiving	Staff survey score.
Confidence Florence will reduce paper use	Staff survey score.
Confidence using Florence after training	Staff survey score.

Table 7. Health and safety considerations.

Social Measure	Activity Measured
Manual handling activities	Number of archive boxes requiring movement.
Manual handling risk	Risks associated with lifting, transporting and storing archive boxes.
Archive transportation burden	Physical handling associated with records management.

Social Sustainability - Wider System Benefits

Table 8. Wider system benefits.

Social Measure	Activity Measured
NHS pathfinder opportunity	Potential for adoption by other NHS organisations.
Evidence generation	Sharing methodology and findings with other Trusts.
Sustainability leadership	Contribution towards NHS Net Zero objectives.
Research capacity	Potential redistribution of staff time from administration to research delivery activities.

Results:

Patient outcome Results

Although this project primarily focused on improving the sustainability of research administration rather than direct clinical care, it is expected to have a positive indirect benefit for patients. The implementation of an eISF improves document accessibility, version control and oversight, enabling research staff to spend less time on administrative and more time on patient facing activities, recruitment and study delivery. Remote access to study documentation also supports more efficient monitoring and quicker resolution of queries, reducing delays in study conduct and helping patients research opportunities more efficiently. It was beyond the scope of this project to directly measure patient benefits.

Population outcome Results:

The project has the potential to improve population health by increasing the efficiency and sustainability of research delivery across the organisation. Reduced administrative burden enables research teams to manage studies more effectively and supports capacity for increased research activity. Improved research efficiency may facilitate faster recruitment into clinical studies, enabling more patients to access innovative treatments while contributing to the generation of evidence that benefits future patient populations. In addition, reducing the environmental impact of healthcare contributes to wider public health by supporting NHS Net Zero ambitions. (NHS England, 2022). It was beyond the scope of this project to directly measure population benefits.

Environmental sustainability Results:

Current pathway

This paper-based pathway had a long inventory for each element, piece of kit and equipment used, transportation and waste management and is shown in Table 9, with the emission factors. The carbon footprint for each item was calculated, then combined for the total emissions. The current paper-based pathway **yearly emissions are 2,186.34 kgCO₂e**.

Table 9. for Inventory for equipment, transport and waste disposal for current paper base pathway.

Item	Quantity	Weight (kg)	Emission factor (kgCO ₂ e per unit)	Carbon emissions (kgCO ₂ e)	Reference
A4 paper	380 (1900 sheets A4 per study)	862.6	1.346 per kg paper	1,158.98	2026 DESNZ
Printer ink / toner cartridge	63.3		3.66 per cartridge	231.8	Carbon footprint TerraJet
Lever arch files	400	0.4kg per file. Total 100kg	1.2870 per kg mixed paper and board	128.7	2026 DESNZ
Dividers, plastic wallets and file labels	400	0.335kg polypropylene per pack/100	2.575	6.6	2026 DESNZ
Pens	50	Approx 90g CO ₂ e per pen	0.09	4.5	
Printer manufacture / embodied carbon allocation	1 printer	(**)	500	500	VersaLink-C415-Environmental-Life-Cycle-Assessment-for-EPEAT.pdf
Printer electricity during printing	190,000 (380 reams of 500 sheets)	0.22W per sheet	0.0000317 kgCO ₂ e per sheet (electricity emissions 0.1440 kgCO ₂ e per kWh)	6.0	Laser Tek blog
Filing cabinets / storage cabinets	2	39kg steel per cabinet	2.86 per kg steel	223.1	2026 DESNZ
Transport of folders to archive (*)	100	1200kg (12kg per study), 33km in diesel panel van	0.8795 kgCO ₂ e per tonne.km	34.83	2026 DESNZ
Future retrieval journeys from archive (*)	100	240 kg (20% retrieved from archive)	0.8795 kgCO ₂ e per tonne.km	6.97	2026 DESNZ
Return transport to HHFT/ destruction provider (*)	100	240 kg based on 20% returned to archive facility	0.8795 kgCO ₂ e per tonne.km	6.97	2026 DESNZ
Archive warehouse lighting	0.5		0.1440 kgCO ₂ e per kWh	7.20	2026 DESNZ
Archive heating/cooling	1.5		0.1440 kgCO ₂ e per kWh	21.59	2026 DESNZ
Archive humidity control	1		0.1440 kgCO ₂ e per kWh	14.40	2026 DESNZ
Archive security systems	0.3		0.1440 kgCO ₂ e per kWh	4.32	2026 DESNZ
Waste transport for shredding/ disposal (*)		1200kg travelling 176km	0.879 kgCO ₂ e per tonne.km	185.64	2026 DESNZ
Courier/postage of documents	100		0.4450 per 200g letter	44.50	Royal Mail LCA
Total emissions				2,186.34 kgCO₂e	

* Transport emissions per journey are calculated by weight of product, distance travelled and emissions per tonne.km travelled. Weight of product transported is 1200 kg (1.2t)

** One office laser jet printer prints 200,000 pages in a lifetime. Embodied carbon ranges from 400 to 800 kgCO₂e

The distance for record storage consists of boxes being transported from Basingstoke to Restore Records Management, Charlcroft Business Centre, West End, Southampton SO30 2PA (which is 30.4 miles) or Winchester hospital to SO30 2PA (which is 10.9 miles) which averages at 20.65 miles (33km) for all boxes. The distance for shredding is 110 miles (176km) from Southampton record store SO30 2PA to Harlow, Essex. The emission factor for diesel Class I vans (up to 1.3t) is 0.879 kgCO₂e per tonne.km.)

Digital pathway - Environmental Sustainability Results

This new digital-based pathway has an inventory for each element, primarily regarding data storage and energy use rather than equipment used, transportation and waste disposal. Table 10 includes the inventory, emission factors for each aspect, total emissions and references. The carbon footprint for each item was calculated, then combined for the total emissions. The **yearly emissions are 129.96 kgCO₂e**, based on 100 studies annually.

Table 10. Inventory for digital storage and energy use

Item	Quantity	Emission factor kgCO ₂ e per unit	Emissions per year kgCO ₂ e	Reference
Digital access - Website use via existing PC desktop computers	130 kWh energy use per year (*)	0.144 kgCO ₂ e per kWh	18.71	Computers - European Commission
Digital access - uploads, downloads and e-signature (**)	50GB	0.025 kgCO ₂ e per GB stored	1.25	CO2e Data Calculator – Digital Decarbonisation
Digital storage - Primary cloud/data storage	50GB	0.025 kgCO ₂ e per GB stored	1.25	CO2e Data Calculator – Digital Decarbonisation
Digital storage - Backup storage / audit trails, data verification	100	0.025 kgCO ₂ e per GB stored	2.5	CO2e Data Calculator – Digital Decarbonisation
Digital storage - Replicated storage / disaster recovery (***)	50	0.025 kgCO ₂ e per GB stored	1.25	CO2e Data Calculator – Digital Decarbonisation
Data centre operations	4200 GB stored (all studies)	0.025 kgCO ₂ e per GB stored	105	CO2e Data Calculator – Digital Decarbonisation
Total emissions			129.96 kgCO₂e	

(* 0.5 hours/week × 52 weeks= 26 hours per user per year. 26 hours × 35 active users = 1,300 user-hours per year. 1300 hours × 0.1 kW =130 kWh per year)

(** A paper archive box containing approximately 1,900 pages was assumed to require 2 GB of long-term digital storage when converted to Florence Healthcare, including backups, replication and preservation overheads. Includes emissions from electricity used.)

(*** Assume all data is backed up.)

Summary of environmental results

Based on 100 studies, the paper pathway generates 2,186.34 kgCO₂e per year, compared with 129.96 kgCO₂e for the digital pathway. This results in an **annual carbon saving of 2,056.38 kgCO₂e** when using the digital pathway.

Economic Sustainability Results:

The financial costs of the current paper-based pathway and the future Florence digital pathway have been calculated based on 100 research studies managed over a 1-year period. The financial modelling also includes a £1000 contribution to Florence costs paid by the study sponsors for commercial research on a per study basis.

The financial model shows that the current paper-based pathway costs £75,639.25 per year, while the future Florence pathway costs £43,566.75 per year. This represents a first-year saving of £32,072.50 through digitisation. This is detailed in tables 11-13 below.

Table 11. Financial cost comparison between paper-based pathway and Florence pathway

Pathway	Main cost areas included	Total annual cost
Current paper-based pathway	Consumables, folders, staff time, transport, archiving, retrieval, return/destruction processes and postage	£75,639.25
Future Florence pathway	Florence platform access, staff time using Florence, website/computer use, helpdesk/system administration, implementation/configuration and staff training	£43,566.75
Annual financial benefit of Florence pathway	Reduction in paper, toner, physical storage, transport, archive handling and related staff time	£32,072.50 saving

Table 12. Cost breakdown: Paper-based pathway

Lifecycle stage	Total cost
Consumables	£15,518.47
Equipment	£429.58
Staff activity, including printing, archiving preparation, retrieval/checking activity and remote monitoring-related staff time	£56,240.00
Transport / logistics	£2,791.20
Physical archiving	£225.00
End of life	£135.00
Courier/postage of documents	£300.00
Total current paper-based pathway	£75,639.25

Table 13. Cost breakdown: Florence pathway

Lifecycle stage	Total cost
Florence implementation cost	£8000
Florence platform access and website use via existing Trust computers	£6,522.75
Staff time using Florence	£24,934.00
Helpdesk / system administration	£137.00
Initial implementation and configuration	£3,288.00
Staff training on Florence	£685.00
Total future Florence pathway	£43,566.75

Potential 5-year savings projection

Using the economic sustainability results, a projected 5-year cost saving calculation has been created using the yearly cost of the paper pathway as a constant reoccurring cost and then removing the 'initial implementation and configuration' cost from the Florence calculations for the remaining 4 years. These figures represent an estimate of the potential savings at the 5-year point.

Table 14. Projected 5-year savings.

5 Year Cost Analysis Projection	Total cost - Paper	Total cost - Florence
Year 1	£75,639.25	£43,566.75
Year 2	£75,639.25	£32,278.75
Year 3	£75,639.25	£32,278.75
Year 4	£75,639.25	£32,278.75
Year 5	£75,639.25	£32,278.75
Totals	£378,196.25	£172,681.75
Projected 5-year savings	£205,514.50	

Based on the updated financial data, the current paper-based pathway costs £75,639.25 per year, compared with £43,566.75 per year for the Florence digital pathway. This delivers an estimated first-year cost saving of £32,072.50 through digitisation. The largest financial benefits arise from reductions in paper consumption, printing, filing, physical archiving, document retrieval, transport and associated staff time.

Whilst the Year 1 analysis demonstrates an annual saving of £32,072.50, this represents a conservative estimate as it includes the one-off costs associated with implementation, configuration and staff training. Once these initial costs have been absorbed, the recurring annual saving is estimated to increase to £43,360.50 per year.

Over a five-year period, the Florence Healthcare pathway is projected to generate a cumulative organisational saving of **£205,514.50** to HHFT. The five-year analysis demonstrates a 54.3% reduction in total organisational costs (£378,196.25 vs £172,681.75), providing a strong long-term financial case for implementation.

Social Sustainability Results:

Data measures for social sustainability are listed in Tables 15, 16 and 17 in Appendix 1.

Key Survey Findings

Survey findings demonstrated strong support for sustainability and digital archiving:

- 87% of staff felt that reducing the environmental impact of research activities was highly important (average score 4.37/5).

1. How important is reducing the environmental impact of research activities to you?



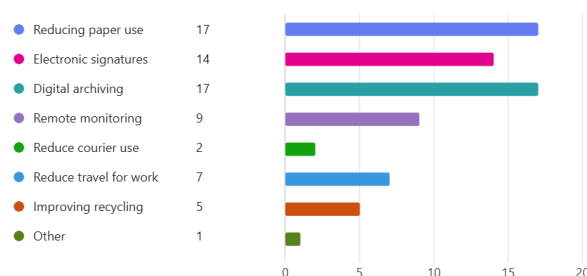
- 88% of staff felt the department should place greater emphasis on environmental sustainability (average score 4.42/5).

2. Do you think the R&D department should place greater emphasis on reducing its environmental impact?



- Digital archiving and reduction of paper use were among the highest-ranked sustainability priorities.

3. Which sustainability initiatives would you most like the department to prioritise? [More details](#)



- 89% of staff reported insufficient storage space for paper ISFs.

8. Do you feel we have sufficient space for storage of paper Investigator Site Files (ISFs) currently? [More details](#)

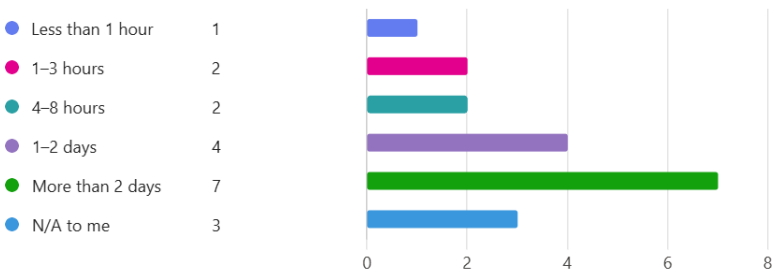


- Staff reported spending significant time obtaining signatures (over 30 mins per signature) and preparing studies for archive (over 2 days per study).

6. Approximately how much time do you spend obtaining a signature for a research document? [More details](#)



11. Approximately how much time do you spend preparing a study for archiving? [More details](#)



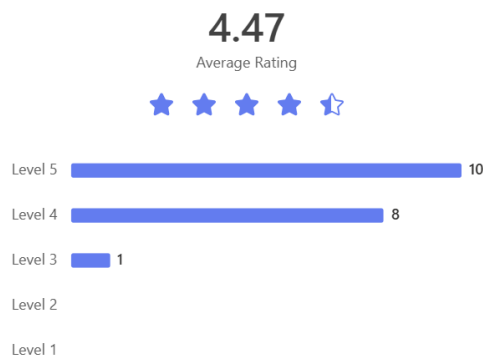
- 89% of staff felt confident that Florence would reduce paper use was high (4.47/5).

13. Given this information, to what extent do you believe Florence Healthcare will reduce paper usage within R&D? [More details](#)



- 89% of staff felt confident in being able to use Florence successfully following training was also high (4.47/5).

14. How confident are you that you could successfully use Florence Healthcare after receiving appropriate training? [More details](#)



These findings strongly support the need for a digital archiving solution to be analysed and highlight key social sustainability measures for evaluation as part of this project.

The staff survey identified a strong desire for more sustainable research practices, with 87% of respondents reporting that reducing the environmental impact of research activity was important and 88% believing the department should place greater emphasis on sustainability. The environmental modelling conducted as part of this project demonstrated that replacing paper-based ISF with Florence Healthcare could reduce associated carbon emissions by 94%, directly addressing one of the key priorities identified by staff.

Staff also highlighted the significant administrative burden associated with managing paper-based study documentation, including obtaining wet signatures, maintaining paper records, preparing studies for archiving and retrieving archived files. Process mapping and financial modelling demonstrated that many of these activities could be reduced or eliminated through use of Florence Healthcare. Electronic document management, version control, remote access and electronic workflows are expected to reduce time spent on administrative tasks, allowing staff to focus more of their time on research delivery and participant-facing activities.

Storage constraints were another significant issue identified through the survey, with 89% of respondents reporting insufficient physical storage space for paper ISF's. Adoption of Florence Healthcare would substantially reduce reliance on physical file storage and long-term paper archiving, addressing a key operational challenge experienced across the department and allowing more space for desks to increase head count in the future.

Survey responses also demonstrated a high level of confidence in the proposed solution, with most respondents agreeing that Florence Healthcare would support reductions in paper use and could be successfully adopted following appropriate training. These findings suggest strong staff readiness for change and indicate that implementation is likely to deliver both practical and cultural benefits within the research workforce.

Beyond individual staff benefits, the project supports wider organisational objectives by creating opportunities to reallocate staffing funding from administrative processes towards funding staffing roles that directly support research delivery and participant recruitment. This has the potential to improve staff experience whilst increasing research capacity across the organisation.

Discussion

The findings demonstrate that digital archiving has the potential to substantially improve the sustainability of research operations whilst maintaining regulatory compliance and governance standards.

The environmental analysis demonstrated that the Florence pathway could achieve an estimated **annual carbon saving of 2,056.38 kgCO₂e**, equating to a **94% reduction in carbon emissions** compared with the existing paper-based pathway.

Financial modelling demonstrated an estimated first-year saving of £32,072.50. Savings were primarily attributable to reductions in paper-based administration, printing, filing, archiving and document retrieval processes. Importantly, this first-year saving represents a conservative estimate because the Florence pathway includes one-off implementation, configuration and training costs. Once these costs have been absorbed, annual recurring savings are projected to increase to approximately £43,360.50 per year. Over five years, cumulative organisational savings are estimated to exceed £205,000, demonstrating that electronic archiving should be viewed not only as a sustainability initiative but also as a significant long-term efficiency investment.

The project also identified important social sustainability benefits. Staff reported high levels of support for environmental sustainability and digital archiving, with most respondents identifying paper reduction and electronic document management as key departmental priorities. Digital archiving is expected to reduce administrative burden, improve accessibility of documentation and support more flexible approaches to monitoring and inspection readiness.

Several challenges were identified during the project. Obtaining robust activity data required multiple modelling assumptions due to the absence of routinely collected information regarding paper use, printing volumes and archive activity. The project therefore represents a modelling exercise rather than a direct implementation evaluation. Additionally, successful adoption of Florence Healthcare will require investment in implementation, user training, information governance assurance, cyber security review and organisational change management.

A key limitation of the work is that direct patient and population outcomes were not measured. The intervention does not alter clinical care pathways and therefore the benefits identified relate primarily to sustainability, efficiency and research capacity. Future evaluation following implementation should seek to quantify actual reductions in paper consumption, archive activity and staff time, alongside measures of research productivity and user experience.

The findings are likely to be transferable to many NHS research organisations facing similar challenges in managing paper-based research records. Wider adoption of compliant electronic Investigator Site File systems could contribute significantly to NHS sustainability objectives whilst supporting modernisation of research infrastructure and improving inspection readiness.

Conclusions

This project demonstrates that transitioning from paper-based ISF's to an electronic archiving platform has the potential to deliver substantial environmental, financial and social benefits whilst maintaining the high standards of governance, compliance and participant safety required within NHS research.

Modelling suggests that implementation of Florence Healthcare could reduce carbon emissions by 94% whilst generating first-year savings of £32,072.50. As implementation and training costs are largely one-off expenses, annual recurring savings are projected to increase to approximately £43,360.50 from Year 2 onwards. Over a five-year period, cumulative savings are estimated at £205,514.50, providing a compelling financial case alongside substantial environmental and social benefits.

Key factors contributing to the success of the project included extensive stakeholder engagement, detailed process mapping, strong staff involvement and alignment with wider organisational and NHS sustainability objectives. These activities enabled development of a realistic and evidence-based assessment of the proposed solution.

The next step is to progress organisational approval, via a successful business case to the trust board, and implementation planning for Florence Healthcare, including procurement, cyber security review, information governance assurance and workforce training. Following implementation, a prospective evaluation should be undertaken to validate the modelled benefits and assess longer-term impacts on research capacity, operational efficiency and sustainability performance.

Appendix 1 – Measure Tables

Table 15. Social Sustainability - Workforce Experience

Social Measure	Activity Results
Time obtaining signatures	Most respondents stated 15 to 30 minutes per signature. With 10+ signatures required per study, this equates to an estimated 6 hours of signature collection per study.
Time preparing studies for archiving	Majority of responders stated: more than 2 days.
Time preparing and supporting monitoring visits	Estimated at 9 hours per study.
Importance of environmental sustainability	87% of responders said this was 'highly important'
Desire for greater sustainability focus	88% of responders said R&D should place greater emphasis on environmental sustainability
Storage pressure	89% of responders said R&D did not have sufficient storage space for ISFs
Support for digital archiving solution	92% of respondents were supportive of a digital archiving solution
Confidence Florence will reduce paper use	89% of responders were confident that Florence would reduce paper usage

Table 16. Social Sustainability - Health and Safety considerations

We recorded:

Social Measure	Activity Measured
Manual handling activities	100 archiving boxes sent to Restore each year
Manual handling risk	84% of staff experienced manual handling issues at least occasionally
Archive transportation burden	Anecdotal evidence suggests studies often required multiple record retrievals before destruction.

Table 17. Social Sustainability - Wider System Benefits

We recorded:

Social Measure	Activity Results
NHS pathfinder opportunity	R&D forum participation and discussion with Florence Healthcare highlighted significant interest to adopt Florence Healthcare as the nationwide electronic ISF management system. HHFT were able to share business case development information with UHS NHS FT and this opportunity could enable HHFT to share onwards with other NHS trusts saving them resource and staff time.

Evidence generation	This sustainability project has enabled us to calculate potential cost and environmental sustainability savings which we can demonstrate at conferences in the future to share the evidence generated.
Sustainability leadership	We have been able to share this evidence generated towards NHS Net Zero objectives with the HHFT sustainability and SUSQI teams.
Research capacity	Potential redistribution of staff time from administration to research delivery activities.

Appendix 2 - References and Resources

Centre for Sustainable Healthcare (2026) Sustainability in Quality Improvement (SusQI): The Sustainable Value Framework. Oxford: Centre for Sustainable Healthcare. Available at: <https://sustainablehealthcare.org.uk/sustainable-quality-improvement-susqi/>

Hampshire Hospitals NHS Foundation Trust (2024) Research and Development Policy (HH1CO58724). Internal policy document. Basingstoke: Hampshire Hospitals NHS Foundation Trust. Available from: Trust intranet (Accessed: 5 August 2026).

Health Research Authority (2017) UK Policy Framework for Health and Social Care Research. Available at: hra.nhs.uk (Accessed: 4 August 2026).

HHFT Green Plan 2025-2028 Available at https://trustnet.hampshirehospitals.nhs.uk/application/files/9217/6165/2575/Green_Plan_2025-28_Version_2_October_2025.pdf (Accessed: 5 Aug 2026)

International Council for Harmonisation (ICH) (2016) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) EMA/CHMP/ICH/2[0156]/2016. Available at: [europa.eu](https://europe.eu) (Accessed: 4 August 2026).

Medicines and Healthcare products Regulatory Agency (2020) Clinical trials for medicines: Compliance with Good Clinical Practice. Available at: www.gov.uk (Accessed: 4 August 2026).

NHS England (2022) Delivering a 'Net Zero' National Health Service. London: NHS England. Available at: <https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf> (Accessed: 30 July 2026).

National Contract Value Review ICT Tariff [How the interactive Costing Tool \(iCT\) calculates the costs of studies at sites | NIHR](#) (Accessed 5th Aug 2026)

Ozdemir, B.A., Karthikesalingam, A., Sinha, S., Poloniecki, J.D., Hinchliffe, R.J., Thompson, M.M. and Boyle, J.R., 2015. Research activity and the association with mortality. *PLOS One*, 10(2), p.e0118253

Appendix 3 – Critical Success Factors

Critical success factors			
People	Process	Resources	Context
☐ Patient involvement and/or appropriate information for patients - to raise awareness and understanding of intervention X Staff engagement ☐ MDT / Cross-department communication ☐ Skills and capability of staff ☐ Team/service agreement that there is a problem and changes are suitable to trial (Knowledge and understanding of the issue) ☐ Support from senior organisational or system leaders	☐ clear guidance / evidence / policy to support the intervention. ☐ Incentivisation of the strategy – e.g., QOF in general practice ☐ systematic and coordinated approach ☐ clear, measurable targets ☐ long-term strategy for sustaining and embedding change developed in planning phase X integrating the intervention into the natural workflow, team functions, technology systems, and incentive structures of the team/service/organisation	☐ Dedicated time ☐ QI training / information resources and organisation process / support X Infrastructure capable of providing teams with information, data and equipment needed ☐ Research / evidence of change successfully implemented elsewhere ☐ Financial investment	☐ aims aligned with wider service, organisational or system goals. ☐ Links to patient benefits / clinical outcomes ☐ Links to staff benefits X 'Permission' given through the organisational context, capacity and positive change culture.