CUSTOMER CASE STUDY NHS RESEARCH · eISF

University Hospitals of Liverpool Group launches AQ eISF in two weeks across a 150+ study research portfolio

Liverpool introduced a controlled electronic site file for **all new studies in two weeks**, replacing fragmented paper and SharePoint processes while migrating its existing study portfolio in manageable phases.

THE CUSTOMER

NHS
University Hospitals of Liverpool
Group

Organisation: University Hospitals of Liverpool Group

Setting: NHS acute & clinical research

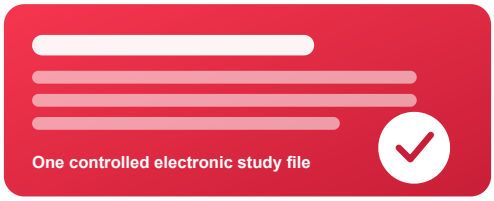
Portfolio: 150+ studies running concurrently

Module adopted: AQ eISF (electronic site file)

BEFORE

AQ eISF

AFTER



150+
Studies running concurrently in the research portfolio

2 weeks
From implementation start to production go-live for new studies

All new studies
Now created in AQ eISF from launch

Phased
Existing studies migrating in controlled phases

Two weeks from implementation commencement to production go-live for new studies. The existing 150+ study portfolio is being migrated progressively; it was not transferred within the two-week period.

THE STORY IN 30 SECONDS

- ✓ **The challenge:** fragmented paper and SharePoint processes across a 150+ study portfolio, with no end-to-end electronic site file.
- ✓ **The rollout:** production go-live for new studies in two weeks, with no AQ-attributable delay.
- ✓ **The choice:** AQ eISF — purpose-built for NHS research, proportionate in cost and effort, and ready for IG/IT assurance.
- ✓ **The approach:** all new studies start in AQ now; the existing portfolio migrates in controlled phases.

01

THE STARTING POINT

Fragmented paper and SharePoint processes

Like many NHS research sites, the team had not operated a purpose-built investigator site file. Documents were held across **SharePoint folders and paper binders**, while the

unit ran **more than 150 studies concurrently**. The existing approach functioned, but carried real operational cost.

Time lost locating documents

Finding and confirming the current, approved version of a document meant searching multiple drives and folders, or retrieving paper binders.

Not governed as an end-to-end eISF

The existing combination of SharePoint folders and paper was not configured, validated or governed as an end-to-end electronic investigator site file. Document versions, permissions and audit evidence were fragmented across different locations.

Physical storage and archiving burden

Paper requires secure long-term storage and retrieval. Across a 150+ study portfolio, the physical storage and archiving overhead continued to grow.

Reactive inspection preparation

Assembling a complete, current and approved file for monitoring or inspection was performed reactively each time, rather than maintained continuously.

✕ BEFORE AQ

- ✕ Documents split across SharePoint folders and paper binders
- ✕ Inconsistent manual version control
- ✕ No end-to-end audit trail across the complete study file
- ✕ Time lost locating current and approved documents
- ✕ Physical storage and long-term archiving burden
- ✕ Inspection and monitoring preparation performed reactively

✓ WITH AQ eISF

- ✓ **One controlled electronic study-file environment**
- ✓ **Document version control and electronic signature workflows**
- ✓ **Traceable document activity and audit history**
- ✓ **Structured access for authorised users and monitors**
- ✓ **Controlled electronic retention and retrieval**
- ✓ **A more continuous approach to inspection readiness**

02 SELECTION & FIT

What Liverpool needed — and how AQ answered it

An electronic site file was clearly required; what mattered was the fit. Liverpool set out the requirements of an NHS research operating model, then assessed how each was met.

LIVERPOOL NEEDED

Proportionate commercial model

Financially viable for an NHS R&D function and able to scale progressively — not a large enterprise commitment up front.

HOW AQ ANSWERED

Modular and proportionate

A cost and implementation model sized for NHS and research teams — modular, scaling with adoption.

LIVERPOOL NEEDED

Rapid, manageable implementation

Introduced without a lengthy internal transformation programme for an already stretched team.

HOW AQ ANSWERED

Two-week go-live

Production go-live for new studies in two weeks, with no AQ-attributable delay.

LIVERPOOL NEEDED	HOW AQ ANSWERED
Straightforward adoption Intuitive for research nurses, coordinators and operational staff, without extensive time away from study delivery.	**Designed for site teams** Built around how site teams work, with train-the-trainer, live sessions, on-demand video and month-one hypercare.
NHS assurance readiness A supplier able to support IG, IT assurance, data protection and procurement with clear documentation.	**Evidence ready for review** Certifications, validation, security, data-protection and continuity documentation prepared for assurance review.
Flexible migration Start new studies electronically while moving existing studies in controlled phases, without disrupting live research.	**New studies first, phased migration** All new studies begin in AQ from go-live; the existing portfolio migrates progressively.

The core of the fit

The challenge was not simply finding eISF software — it was finding a platform that matched the operating realities, resources and assurance expectations of an NHS research organisation. AQ was built with NHS research teams, for exactly that.

> **"AQ understands our challenges and has co-developed a solution that will work not just for our Liverpool research unit, but for any NHS research unit."**

R&D Lead
University Hospitals of Liverpool Group

IMPLEMENTATION AT A GLANCE

- ✓ Two weeks to production go-live
- ✓ New studies created in AQ eISF
- ✓ Phased migration underway
- ✓ No AQ-attributable delay

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IMPLEMENTATION & ENABLEMENT

Production go-live in two weeks, with no AQ-attributable delay

AQ completed implementation, enablement and assurance without causing a delay to the agreed production launch. Enablement was designed to fit a team with limited spare capacity.

2 weeks **From implementation start to production go-live** for new studies — with no AQ-attributable delay during configuration, training and IG/IT assurance.

STEP 01

Train the trainer

In-house champions equipped to support their colleagues.

STEP 02

Live online sessions

Guided training for the wider research team.

STEP 03

On-demand videos

Self-paced learning and onboarding for new joiners.

STEP 04

Hypercare — month 1

Hands-on support through the early adoption window.

04

LAUNCH & MIGRATION

New studies first, with existing studies migrating in phases

With a 150+ study portfolio, a single cutover was not the goal. The approach was deliberately staged so live research was not disrupted.

FROM GO-LIVE

All new studies begin in AQ eISF

Every new study is created in the controlled electronic site file from the agreed launch date, so the volume of fragmented, paper-based files stops growing.

ONGOING

Existing studies migrate in controlled phases

The existing portfolio is moved onto the platform progressively, in manageable phases, without interrupting active studies.

05

RESULTS

Outcomes to date

The following outcomes are supported by the implementation to date.

- **Production go-live in two weeks** from implementation commencement, for new studies.
- **No AQ-attributable delay** during configuration, training and IG/IT assurance.
- **All new studies now begin in AQ eISF**, creating a repeatable study set-up process.
- **Phased migration underway** for the existing study portfolio, without disrupting live research.

- **Faster document retrieval** and reduced reliance on paper, with controlled electronic storage.
- **Improved ability to prepare** for monitoring and inspection activity through a more continuous approach.

Minutes → seconds

Document retrieval, before and after AQ — from manual searching across drives and binders to near-instant retrieval.

100%

Of new studies now created in AQ eISF since go-live.

~250 hrs / month

Estimated research-staff time returned from reduced document filing, searching and version control.

Time-saved basis: approximately 30 research staff each saving around two hours per week on document filing, searching and version control (≈ 30 × 2 hrs × 4.3 weeks ≈ 250 hours per month).

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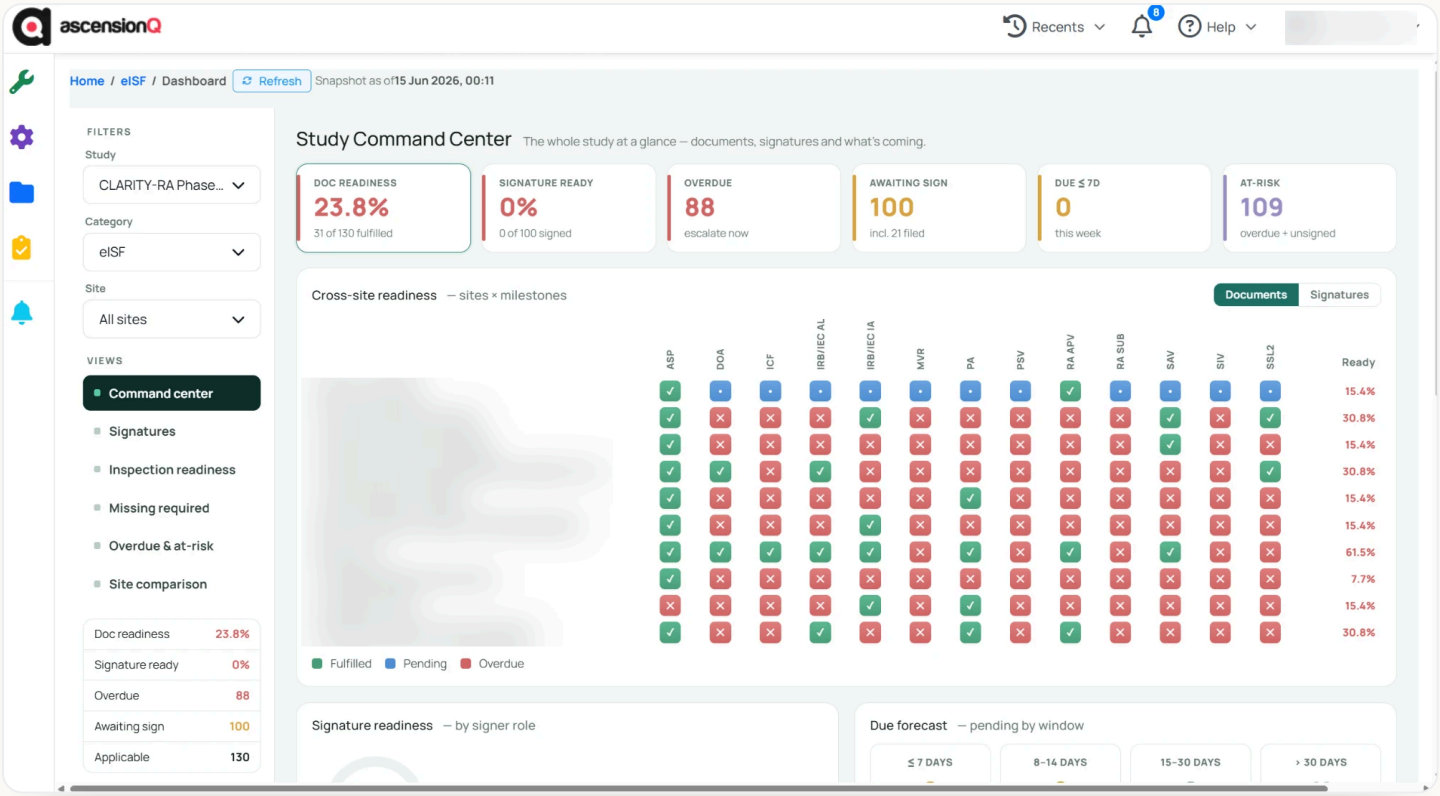
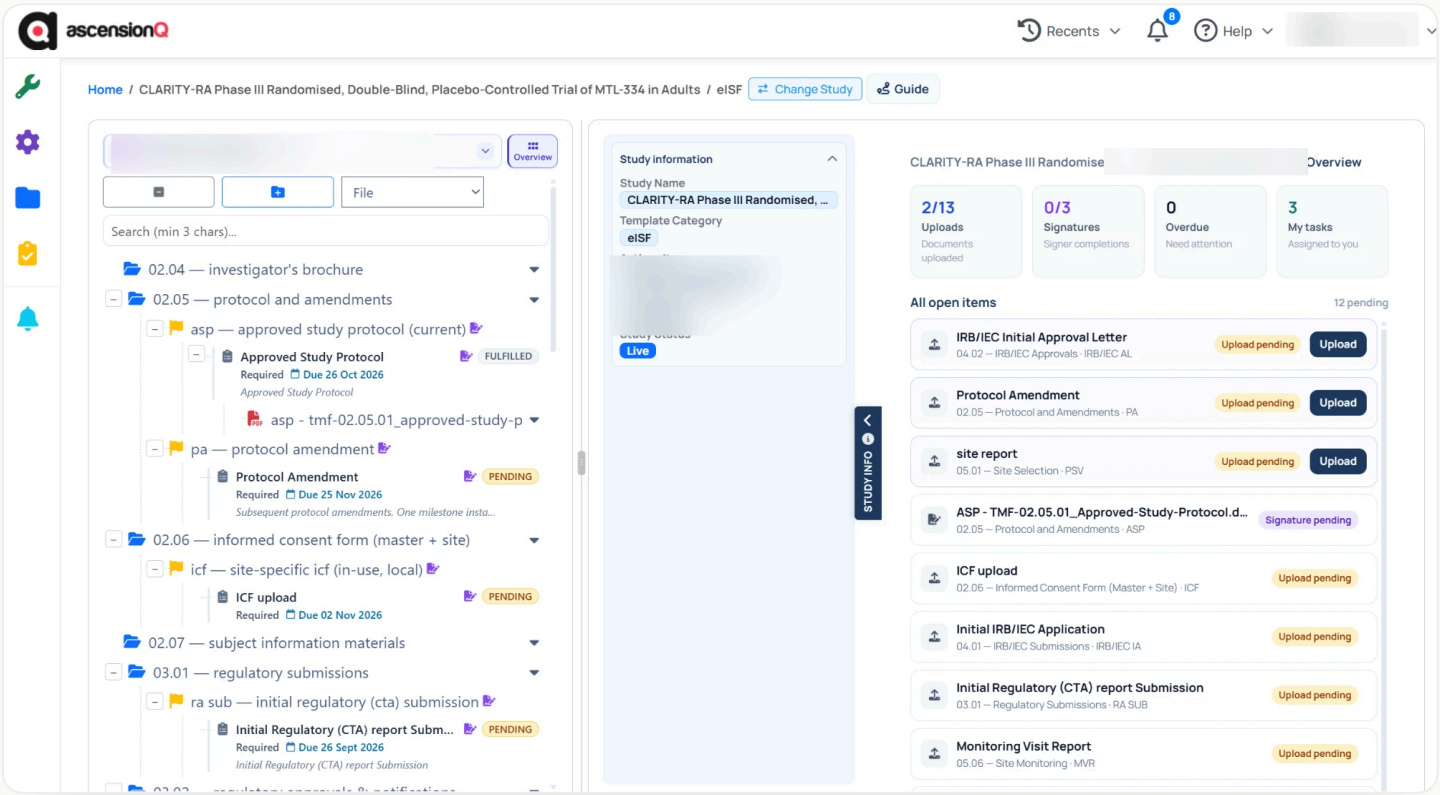
INSIDE AQ EISF

A controlled, traceable study-file environment



Study Command Center — cross-site document and signature readiness, with overdue and at-risk items surfaced. Site names redacted for confidentiality.



Study file structure — required documents by section, with statuses, due dates and open tasks. Site and personal names redacted for confidentiality.

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ASSURANCE & REGULATORY SUPPORT

Designed and documented to support regulated use

AQ provides documentation to support information governance, IT assurance, data protection and procurement review. Items are grouped by what AQ holds, what evidence is available, and what the platform is designed to support.

INDEPENDENT CERTIFICATIONS & REGISTRATIONS

Held by AQ

- Cyber Essentials
- ICO registration: ZB324099

ASSURANCE EVIDENCE AVAILABLE

Provided to support review

- NHS Data Security and Protection Toolkit submission
- System and supplier validation documentation
- Information security documentation
- Data protection documentation (UK GDPR / DPIA)
- Business continuity and disaster recovery evidence
- Penetration-testing summary
- Hosting and data-residency information
- Supplier assurance documentation

DESIGNED TO SUPPORT

Mapped against relevant expectations — alignment, not certification

- ICH E6(R3)
- Applicable UK Clinical Trials Regulations
- UK GDPR and Data Protection Act 2018
- MHRA expectations for computerised systems
- 21 CFR Part 11 electronic record and signature requirements
- GAMP 5 principles
- ALCOA++ data-integrity principles
- ISO 27001 and ISO 22301 control principles (alignment)
- NCSC Cyber Assessment Framework principles

UK-hosted environment

AQ supports controlled electronic archiving and retrieval in accordance with applicable UK clinical-trial retention requirements, including 25-year retention where required under the amended UK clinical trial regulations. Applicable retention periods depend on the type of research, regulatory route, study submission date, sponsor requirements and relevant legislation.

AQ provides a configurable platform together with supporting documentation. Achieving and maintaining regulatory compliance also depends on the organisation's own configuration, validation, procedures and oversight. ISO control principles are referenced as alignment unless formal certification is stated.

NEXT STEP

See how AQ eISF could fit your NHS research organisation

Book a focused demonstration based on your study portfolio, document processes and assurance requirements.

Book an NHS eISF demonstration →

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UK-hosted environment

AQ supports compliant operation through configurable controls and documentation; regulatory compliance remains subject to appropriate configuration, validation and organisational procedures.