

Increasing Commercial Clinical Research in the NHS

Pioneering New Standards in NHS Clinical R&D Commercial Partnerships through IAOCR Workforce Quality Accreditation

OVERVIEW

In 2019 London North West University Healthcare (LNWH) NHS Trust Research and Development Department achieved the Foundation and Bronze level Workforce Quality Accreditations (WQA) for Clinical Research Sites. This case study provides an introduction to clinical research in the NHS, a background to the LNWH NHS Trust's achievements and challenges, an insight into their WQA assessment journey and details of what the WQA has delivered for them within the first six months of achieving accreditation – both in terms of qualitative feedback and quantitative return on investment (ROI).

IAOCR WQA is one of the two foundation blocks that underpins the modular GSCA accreditation.

Further details about GSCA, IAOCR and Workforce Quality Accreditation can be found at the end of this case study.



Take Away

The pioneering Workforce Quality Accreditation (WQA) achieved in 2019

has enabled London North West University Healthcare NHS Trust to attract more commercial clinical research to the NHS and deliver benefits for the NHS workforce:

Attracting More Commercial Clinical Research:

- Approached to undertake a study with potential to generate £80,000 income for the Trust, shortly after achieving WQA
- WQA has helped to build a pipeline of four further studies which could generate an income of between £250,000 - £400,000
- Improvements made as a result of the WQA process have led to an increase in positive feedback from client meetings

Benefits for NHS Workforce:

- Improved staff engagement, ownership and support through attending to staff views uncovered during WQA process
- Staff have reported increased confidence in their own ability to deliver excellent client service.
- Process improvements galvanized through WQA have fostered improved career development and cross-departmental cooperation.



Clinical Research in the NHS

Clinical research represents a high value and essential global industry that is highly-competitive and fast-evolving. The global clinical trials market was estimated to be worth £38.1 billion in 2019, and provides immeasurable value to patients.

The NHS is the UK's public healthcare system and one of the world's largest employers with a workforce of around 1.7 million people. Collectively it includes NHS England, NHS Scotland, NHS Wales, and the affiliated Health and Social Care (HSC) in Northern Ireland. NHS England operates based on a system of NHS Trusts, an organisational unit generally serving either a geographical area, tertiary services or a specialised function, such as an ambulance service.

The NHS is an integral part of the clinical research industry in the UK, supporting both commercial and non-commercial arms in order to bring innovative new treatments to patients. According to a report commissioned by the NIHR CRN (UK's National Institute for Health Research Clinical Research Network), clinical research generated an estimated value of £8 billion of gross added value and 47,467 full time equivalent jobs for the UK over the three-year period spanning the financial years 2016 – 2019.

LNWH Trust – A Reputation for Pioneering Excellence

The London North West University Healthcare NHS Trust is one of the largest integrated care trusts in the country and the Trust's Research and Development (R&D) Department has a long-standing reputation for pioneering excellence. The Trust cares for a population of over a million people in the region of north west London. With over 3,000-5,000 clinical research trials participants recruited each year they have a good patient recruitment and research record and, as part of their commitment to supporting research across the sector, they have spearheaded a number of national initiatives including:

1. Introducing a patient retention and transfer model for patients recruited for research studies treated at a main treatment centre who are subsequently transferred to their local care provider> Previous work includes stroke patients from hyper-acute stroke units to local NHS Trusts after primary treatment, ensuring they stay in the assigned clinical trial and this promoted improved working with partner trusts.
2. Designing an innovative process and contract to transfer patients from NHS organisations into commercial Phase 1 units; which successfully passed HRA (Health Research Authority) review.



3. Working with the School of Pharmacy at University College London (UCL) to develop a pharmacy training programme for “Qualified Persons” focused on improving clinical trial pharmacy support for NHS and commercial clinical trials
<https://www.ucl.ac.uk/pharmacy/study/qualified-persons-training/qualified-person/>;
4. Formed one of the first Patient Research Forums in the North West London area with patients supporting researchers with the designing, training, document development and methodology. The forum is integrated into the day-to-day working of the R&D Department. This model was subsequently adopted by other Trusts within and outside the area.

To further demonstrate their commitment to clinical research and in support of their focus on being a leader in developing best practices and raising standards throughout the NHS clinical research sector, the Trust pioneered the IAOCR Clinical Research Site Workforce Quality Accreditation (WQA) in 2019 becoming the first NHS Trust to undergo WQA assessment and also the first NHS Trust to commence their journey towards the new Global Clinical Site Accreditation (GCSA) of which WQA is an essential foundation module.

More Innovative Treatment Options for Patients Through Increased Commercial Clinical Trials

The two organisations came together through the IAOCR Clinical Research Industry Leaders Think Tank, supported by Jonathan Sheffield, CEO of the UK’s NIHR CRN. As a key member of the Think Tank community Dr Alan Warnes, Assistant Director of LNWH R&D Department, identified a unique opportunity to pioneer accreditation within the NHS, aligning LNWH R&D to work seamlessly with commercial organisations.

Building on established standards for clinical research, in 2019 the LNWH NHS Trust R&D Department underwent the thorough independent accreditation process. The focus was on evaluating processes and performance systems aligned to competence and engagement to ensure a “quality built in” approach to providing best-in-class services to clinical trials patients and commercial partners, centred around workforce excellence.





Goals – Drivers for Accreditation

To demonstrate commitment to their patients and research, the LNWH NHS Trust R&D Department wanted to have their processes and performance systems independently evaluated to gain a true insight into how well they were servicing their clients and supporting their employees.

“As a department within an NHS Trust, we recognised we needed to differentiate ourselves from the commercial and non-commercial competition and evidence that we work to international best practice standards,” said Simon Lewis, Head of Research Operations & Governance, LNWH. “The Department recognised that the IAOCR Workforce Quality Accreditation assessment process would provide a clear solution to a number of challenges, by placing workforce at the centre of the business.”

Prior to commencing the accreditation process the following business goals and drivers for WQA accreditation were identified:

Drivers for Accreditation

1. Stay ahead of the competition through better performance;
2. Stand out as an attractive and competitive place for commercial companies to run their clinical trials;
3. Be an employer of choice – improve staff interactions, engagement, performance and career opportunities through involvement in clinical research and robust people processes and performance management systems.

Business Goals

1. Workforce and processes – ensuring alignment with industry to establish trust and confidence with the commercial sector and increase commercial output;
2. R&D Workforce Roles – ensuring everyone understood the valuable contribution they made, knew they were valued and that they were working to good quality standards;
3. Identifying skills gaps and raising best practice across the department with identifiable information.

The WQA Process

The WQA assessment included a detailed review of the Trust’s organisational-level policies and procedures for LNWH’s R&D Department, validated through online surveys and face-to-face interviews with staff. Feedback and information was gathered from all staff in the Department spanning Delivery, Governance, Pharmacy & Radiology areas of the organisation.

LNWH provided information on high level organisational imperatives such as how employees align to the organisation’s strategy, as well as detailed information on their training, competence verification and accreditation processes. Broadly the assessment for the Foundation and Bronze levels covered:

- Appropriate job descriptions;
- Access to core

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“The assessment process was robust and engaging, yet not time-consuming,” said Simon Lewis, Head of Research Operations & Governance, LNWH. “The feedback gathered as part of the accreditation assessment process was incredibly valuable as it highlighted gaps where we could make improvements. Staff enjoyed the consultation process and found the whole experiencing motivating, they felt like they had an opportunity to help improve things and take ownership.”

technical skills

- training programmes;
- “Red flag” system for identifying lack of competence in high risk areas (patient safety, data integrity, business critical areas);
- Robust and systematic performance appraisal/management systems.



Outcomes

Within six months of achieving the Foundation & Bronze level WQA, LNWH NHS Trust R&D Department has evidenced they are...

... a true EMPLOYER OF CHOICE

- WQA has helped to attract new talent to the organisation;
 - Staff have reported increased confidence in their own ability to deliver excellent client service;
 - Staff felt valued and their views were taken on board, which improved ownership and support throughout the department;
 - Process improvements galvanised through WQA have fostered improved career development and cross-departmental cooperation;
- Improved staff engagement, ownership and support through attending to staff views that were uncovered during the WQA process.

...a PARTNER OF CHOICE FOR COMMERCIAL CLINICAL TRIALS

- Shortly after achieving WQA, the Trust was approached to undertake a study, which has the potential to generate £80,000 income for the Trust;
- WQA has helped to build a pipeline of a further four studies which could generate income between £250,000 and £400,000;
- Clients are reassured by the independent nature of the WQA – LNWH R&D Department has a skilled, engaged, high quality workforce throughout the department;
- WQA evidences commitment to efficiency, quality and value for money;
- Improvements made as a result of the WQA process have led to an increase in positive feedback from client meetings;
- WQA has heightened the profile of research within the organisation, which can be barrier for some R&D departments in large organisations.



Cont.

...a PIONEER OF EXCELLENCE WITHIN THE NHS

LNWH NHS Trust R&D Department:

- Is the first NHS Trust to achieve the WQA, highlighting to industry their efficacy of working;
- Have been shortlisted for two prestigious Health Service Journal awards in the following categories 'People & Organisational Development Initiative of the Year' and 'Operations and Performance Initiative of the year';
- Can confidently provide additional competitive resource for commercial clinical research in the NHS;
- Have implemented best-in-class workforce quality standards, having addressed identified gaps in workforce development, management and processes. These were improved by restructuring ways of working and revaluating systems and processes.

Independent Assessment of LNWH

LNWH met all requirements for the Foundation and Bronze level WQA awards and in many areas excelled. In a like-for-like comparison, IAOCR noted that LNWH R&D Department outperformed many commercial organisations in some areas. Areas of excellence were identified as follows:

Risk Mitigation & Patient Centricity

LNWH has a number of well documented and robust processes which outline the potential risks within the organisation and how they can be mitigated. From the group sessions and one-to-ones, there was a very strong sense of the need to put patient care at the heart of everything that takes place in clinical research and the wider organisation which is to be commended.

Focus on Development of Technical Competence & Access to Senior Staff

There are excellent documents for staff outlining the range of learning opportunities available to them to reach technical competence. There was strong evidence of more senior staff making themselves available to employees in the early weeks and months of their employment.

Values-Aligned Performance Management & Focus on Employee Clinical Research Experience

LNWH has an excellent appraisal system which focusses both on the 'what' (specific objectives for each employee), as well as the 'how' – aligned to their HEART values (Honesty, Equality, Accountability, Respect, Teamwork). Very few organisations have this balance in the way they carry out staff assessment. There was a genuine sense that the wider line management team, within the inevitable demands of workload, were making real efforts to improve the employee experience in clinical research.



About GCSA

Global Clinical Site Accreditation is a global standard that puts patients at the heart of clinical research. Its purpose is to increase capacity and quality of clinical research to bring more innovative treatment options to patients.

The robust and independent GCSA standard fosters seamless collaboration between Sponsors/CROs and Clinical Research Sites through a transparent, objective and consistent assessment process.

GCSA takes a modular-based approach to assessment and accreditation, awarding certification marks as site organisations progress through the 6 key stages of the client and patient journey, and upon passing assessment of the two foundation modules that underpin the patient and client experience: R&D Commercial Strategy and Workforce Quality (which integrates IAOCR's Bronze Level Workforce Quality Accreditation).

GCSA accreditation standards have been developed to address industry needs and are ratified by the GCSA Global Advisory Board, which consists of representatives from the world's leading clinical research organisations.



About IAOCR



IAOCR is the International Accrediting Organisation for Clinical Research. It was founded in 2011 in direct response to demands from industry for global standards for clinical research workforce. Over the past nine years IAOCR has:

- Pioneered and facilitated an initiative focused on supporting a “Significant Growth Opportunity for the UK Clinical Research Sector Pre-Brexit and Beyond”. This involved bringing together industry leaders in a post-Brexit vote Summit Meeting, presenting a white paper to the Prime Minister and subsequently working with the Dept of Health and NIHR on the Patient Recruitment Centres concept.
- Worked with industry to develop a broad range of “Internationally Qualified Professional” standards of accreditation for clinical research professionals working in a wide variety of roles. The Qualified Professional accreditations are widely-recognised as the industry gold standard in terms of robustness and being internationally recognisable.
- Pioneered robust and meaningful accreditation of individuals, training courses and organisations across the clinical research supply chain.
- Led a number of IAOCR Clinical Research Industry Leaders Think Tanks in the UK and USA, bringing together clinical research senior leaders, Regulators and Parliamentarians to address issues and shape best practices.

Pioneered the development of Core Global Competency Frameworks which are now used by the world's leading clinical research organisations.



About WQA

Workforce Quality Accreditation (WQA) is an internationally consistent workforce quality standard developed by IAOCR in association with global pharmaceutical companies and contract research organisations. WQA consists of four levels: Foundation, Bronze, Silver and Gold. Accreditations are awarded at an organisational level upon assessment of evidence that key processes and procedures related to workforce engagement and competence linked to organisational strategy are embedded within the organisation.

WQA is a clearly recognisable quality mark that evidences an organisation is committed to working to the best practice workforce quality standards that differentiate leading clinical research organisations. The independent and evidence-based assessment examines how business strategy is translated into workforce performance.

The overall result of WQA is “quality built in” at the workforce level, thus leading to the high quality, high engagement and high capacity desired by high performing organisations and teams.

What's Next

During 2020 London North West University Healthcare NHS Trust continues to demonstrate commitment to pioneering excellence, embarking on assessments for accreditation in the other GCSA modules following a consultative gap analysis workshop.