

Royal Berkshire NHS Foundation Trust Team Evidence World-Class Status by Achieving Full GCSA Certification

Reading, Berkshire and Maidenhead, United Kingdom, 13 May 2024 – The Research and Innovation Team at Royal Berkshire NHS Foundation Trust Team today announced they have been awarded full [GCSA](#) Certification – The Global Quality Standard for Clinical Research Sites, ratified by The International Accrediting Organisation for Clinical Research (IAOCR). This achievement demonstrates the Research and Innovation Team’s ongoing commitment to being a world-class site and its determination to be a first choice for commercial clinical research, so that they can provide innovative new treatment opportunities for patients. The Royal Berkshire NHS Foundation Trust is the first NHS site to achieve full certification.

The certification correlates with the first day of the RDF24, a UK wide professional community in research management, support & leadership in health and care, where the Trust will present a poster on their latest improvements including their GCSA Certification. GCSA assesses and recognises sites that have robust and effective business operating processes to ensure they can provide the highest quality services to patients and sponsors/CROs. The full GCSA Certification follows Royal Berkshire NHS Trust’s involvement in the GCSA pilot that was fundamental in completing the development of the internationally recognised certification standard for clinical research sites. This GCSA Certification provides reassurance to sponsors, CRO’s, staff - and ultimately to patients, that research sites have been independently assessed against robust global quality standards and that research is in safe hands.

“We are committed to developing new treatments, understanding and preventing illnesses, and improving our patients’ quality of life which is why we chose to progress to the full GCSA Assessment. The pilot process helped build our confidence that our processes, procedures and team are operating at the highest level and so it was important to seek full certification to further build our confidence in our abilities, thus allowing us to pursue boundary-pushing trials,” remarks Dr Janet Lippett, Chief Medical Officer. “This assessment also reinforced the commitment of the whole team to drive up standards and work at a world-class level, which is something we take very seriously. We also value the recommendations made by the GCSA team, which will help us to further enhance our offering.”

The certification was awarded following the GCSA evidence-based assessment of the Royal Berkshire (a District General Hospital) research site operational processes. The supportive and transformative assessment process involved a review of the research business operational procedures and processes covering the following seven critical areas: Governance, Workforce Quality, Site Business Strategy, Patient Engagement, Feasibility, Study Start-Up & Initiation and Study Management Operations & Close-Down. To achieve GCSA Certification (verified by the International Accrediting Organisation for Clinical Research - IAOCR). NHS sites undergo the same rigorous assessment that is applied to commercial clinical research sites undergoing the process, driving up industry standards overall.

“GCSA team applauds Royal Berkshire’s Research and Innovation Team’s commitment to quality as well as the positive workplace environment that provides a great foundation stone for success. The Research and Innovation Team demonstrated a highly commendable working ethos where it is clear that innovation and training is a focus for everyone,” remarked Sarah Everitt, VP Operations for GCSA & IAOCR. “We found all staff were extremely professional, transparent and supportive of the process. This enthusiasm and support has driven their commitment to achieving and maintaining the highest Global quality standards which will help to drive up industry standards as a whole.”

The GCSA quality standard for clinical research sites was developed with the support of a Global Advisory board of key stakeholders and experts from across the industry. Whilst clinical research is a

highly-regulated industry, until now there have been no established standards by which sites can demonstrate that they are able to meet the expectations of sponsors, CROs and patients, and no way for sponsors or CROs to select clinical research sites based on clear quality criteria which have been independently assessed at the organisational level. GCSA sets this much-needed industry standard for research sites, enabling sites to evidence and communicate their capabilities and differentiate in a crowded and increasingly competitive marketplace. Beyond the assessment and certification process, where required, GCSA works collaboratively with sites that need help to achieve certification.

To learn more about IAOCR and GCSA how we can support your business please visit iaocr.com and gcsaassessed.org, or email info@iaocr.com or info@gcsaassessed.org. Alternatively, for both organisations you can call:

- International: +44 1628 784906
- US Toll Free: +1 855 209-2335
- UK: 01628 784906

For further press information please contact: pr@iaocr.com or info@gcsaassessed.org.

<< ENDS >>

Notes to editors

About Royal Berkshire NHS Foundation Trust, Research and Innovation Team

The Research and Innovation (R&I) Department at the Royal Berkshire NHS Foundation Trust, comprises of clinical delivery teams, a number of support departments, alongside our governance team and a number of highly skilled researchers who deliver quality research.

Our R&I department is governed by the R&I Committee that oversees our work and actively promotes a vibrant research culture and community. This committee comprises members of our R&I Core team, key executive members of the Trust, leading research clinicians, and peers from the University of Reading. The R&I department is dedicated to driving continuous improvement to enable our patients to access new treatments through clinical research and innovation.

We work with our local community and in partnership with a number of stakeholders, including universities, industry and other NHS organisations to develop world-class clinical research.

About the International Accrediting Organisation for Clinical Research

The International Accrediting Organisation for Clinical Research (IAOCR). We are the only organization in the world to provide accreditations for clinical research professionals that are internationally recognisable, and assess competency standards set by the global clinical research industry.

Through robustly accrediting clinical research professionals based on evidence of competence, IAOCR reduces risk to patients, clinical research and organisational reputations - whilst improving compliance and bringing valuable new treatments to market more quickly and safely.

IAOCR competency verification, assessment, accreditation and consulting processes are built specifically for the clinical research industry. They work collaboratively with industry experts and organisations globally to provide quality standards and visible professional certification marks that are the international marks of quality for people and organisations working in the clinical research space..

IAOCR believes that clinical trial patients anywhere in the world deserve the best protection in terms of rights and wellbeing.

About GCSA

GCSA is the global quality standard for clinical research sites. Consisting of seven key modules agreed with the industry, it ensures clinical research sites are working to robust and effective processes so that they can deliver world-class services to patients and sponsors. The GCSA framework was developed over 4 years with industry research and engagement, and continues to evolve with the support of a Global Advisory Board of leading industry representatives from the not-for-profit and commercial sector, including leading global Sponsors and CROs, NHS, charitable and commercial clinical research sites, patient groups and other leading healthcare organisations.

The standard has been built to ensure that sites build their processes with the patient experience as their primary focus, and also to facilitate synergistic working between sites and sponsors to enable better patient outcomes. It provides potential sponsors with an assurance of capability through passing independent assessment based on standards and expectations specified by sponsors. Furthermore, GCSA aims to increase clinical research through alignment with commercial requirements, which also increases opportunities for participation and inclusion.