

CLINICAL TRIAL ASSISTANT

Norwich Clinical Trials Unit
Norwich Medical School

SC4795

CANDIDATE BROCHURE



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WHAT MAKES UEA SO SPECIAL?

The University of East Anglia is a publicly funded major UK research and teaching university. It was built to embody a radical new vision for higher education, where interdisciplinarity is crucial and excellence in both research and teaching is valued. UEA consistently ranks within the top quarter of universities in the UK for the quality of research and teaching.

As a major regional employer and cultural centre, we take our regional civic responsibilities very seriously and have kept our sights on the people and place we call home. In fact, we launched our University Civic Charter in October 2023; created from in-depth community engagement, renewing our commitment to the region as part of our 60th anniversary.

There are many things which make UEA special, not least of which is the community of staff and students that work and study here. UEA includes three Nobel prize winners, including Sir Paul Nurse and Sir Michael Houghton, and many fellows of the Royal Society and British Academy amongst our alumni and current staff.

Our campus is home to Sir Denys Lasdun's iconic brutalist architecture set in hundreds of acres of beautiful country park that includes a large broad (lake). In the spirit of Lasdun's ambition to inspire an anatomy of ideas, today, UEA is tackling some of the key challenges of the changing world. UEA's research combines disciplines

and breaks new boundaries across its priority research themes of climate, creative and health.

UEA is the place where global warming was first documented. Since the 1970s, UEA's Climatic Research Unit, and more recently Tyndall Centre for Climate Change (Headquarters hosted at UEA), have played a pivotal role in developing temperature records and climate models, contributing to the understanding of climate change, and informing global policy. Our Professors Corinne Le Quere, Rachel Warren and Robert Nicholls were recipients of Nobel Peace Prize (2007), awarded to Al Gore and the Intergovernmental Panel for Climate Change (IPCC) in recognition of efforts to increase public knowledge of anthropogenic climate change. Environmental Science and Global Studies at UEA continue to be a major powerhouse for research and teaching.

UEA is widely regarded as a pioneer in creative writing, having established the UK's first Creative Writing Masters programme in 1970. This renowned programme has since attracted and produced numerous successful writers, including Booker Prize winners such as Ian McEwan and Anne Enright, and Nobel Prize Winner Kazuo Ishiguro. In recent years, UEA academics have played a pivotal role in the discovery and presentation of the Gloucester Royal shipwreck (Norfolk's Mary Rose). Our iconic Sainsbury Centre for Visual Arts is a major museum and arts research facility.



Health research at UEA not only embraces the Faculty of Medicine and Health but draws in research from both social and natural sciences. Research under this theme has made major contributions in the fields of healthy ageing, epidemiology and involving citizens (via our innovative Citizens' Academy) in improving health care outcomes. This theme benefits from close association with the other major research institutes on the Norwich Research Park; notably the Norfolk and Norwich University Hospital and the Quadram Institute. The Norwich Cancer Research Network, and Norfolk Institute for Healthy Ageing, are examples of key mechanisms for delivery of real impact from health research at UEA.

UEA has been a major success over the last 60 years and looks forward with confidence to the next 60 years.

For an informal discussion about the post please contact Erika Sims via e.sims@uea.ac.uk.

UEA is part of the Norwich Research Park

Norwich Research Park (NRP) membership locates UEA in one of the largest concentrations of research institutes in the whole of Europe – four independent internationally-renowned research institutes: John Innes Centre, Quadram Institute, Earlham Institute and The Sainsbury Laboratory; with the University of East Anglia and Norfolk and Norwich University Hospitals NHS Foundation Trust, supported and funded by The John Innes Foundation, The Gatsby Foundation, and UKRI Biotechnology and Biological Sciences Research Council.

The NRP provides an ideal environment for collaborative use of infrastructure and facilities, with a single portal for academics and businesses to access the specialist facilities across the Park.

The Enterprise Centre is a regional business, knowledge and innovation hub, with workspace provision and supports over 80 businesses working alongside UEA staff and students in a dynamic and vibrant entrepreneurial community. On the wider NRP, there are dedicated laboratory and office spaces in the Innovation Centre and Centrum hosting over 600 staff within a total of 115 businesses and spinouts.



OUR BENEFITS

UEA offers a fantastic benefits package for staff. We recognise all our staff have different priorities and lifestyles so we are continually reviewing our offering to ensure there are benefits which suit everyone. Current benefits include:



Competitive Rates of Pay



20 Days Holiday



14 Additional Statutory and Customary days



Contributory Pension



Staff Development



Sportspark Discount



Research Support



Health and Wellbeing



Library



Campus Facilities



Care Leave Policies



Sainsbury Centre for Visual Arts



Ofsted Outstanding Nursery



And much more!

Further information can be found on our [Staff Benefits page](#).

THE ROLE

KEY RESPONSIBILITIES

- Assist Trial Managers in setting up and maintaining filing systems for study documentation and correspondence; both electronic and paper including a regulatory compliant Trial Master File (TMF). Ensuring that the TMF is inspection ready at all times.
- With the Trial Managers, maintain a close working relationship with investigators and site staff. Ensure prompt and efficient response to queries (Daily trouble shooting) from recruiting sites, escalating to Trial Manager, Research Lead, or Chief Investigator as appropriate.
- Contribute to CTU trial set-up activities including development and critical review of trial 'essential documents' (e.g., patient information sheet, informed consent form, trial management documents and site file documentation).
- Assist the Trial Manager with site setup, ensuring that research sites have the appropriate documentation for site activation and have received training on trial procedures.
- Develop and/or critically review and/or QA: case report forms and other trial specific data management documentation, including working instructions for sites on data management.
- Ensure that trial specific data management documentation is adhered to.
- Perform testing of the Study Database prior to release to sites, documenting non performances and following through with the Trial Manager and Data Management Team to resolution.
- Check and process Case Report Forms received by the CTU, including data entry when required.
- Check and process SAE forms received by the CTU, including scanning for patient identifiers and redacting any personal information, scanning for completeness of form and following up with sites immediately for missing essential data; ensuring that the SAE flow for confirmation of expectedness and causality and timely clinical review is completed. Enter SAE data into SAE database, close out SAEs, log and file forms in the Trial Master File.
- Under the supervision of the Trial Managers, ensure compliance with the trial Quality Management and Monitoring Plan which includes remote data monitoring and some on-site monitoring.
- Perform Central Monitoring through review of data in the trial database as described in the trial specific QMMP. Ensure efficient query management and resolution, quality control, data cleaning and validation.
- Enter trial information into the Integrated Research Application System, trial safety reports, and other reports including to the Funder, Sponsor and Research Ethics Service.
- Process and graph/tabulate CONSORT and accrual data.
- Collate, validate and upload submission of trial accrual data to the UKCRN portfolio and other related third parties.
- Assist with updating the study website and production of newsletters, regular and ad hoc trial reports and manuscripts for publication as requested.
- Manage trial supplies and distribution to sites, ensuring that all collaborators are supplied with appropriate materials.
- Provide general office management, delegating to CTU administrator depending on priorities, to keep operations running smoothly.
- Undertake general office duties such as maintaining stationery and other similar items, in the absence of the CTU administrator.
- Contribute to trial team meetings.

THE ROLE (CONTINUED)

- Contribute to the creation of trial specific working instructions.
- Arrange trial meetings, preparing agendas and typing minutes.
- Coordinate communication with the external parties including Trial Governance Committees, Funders, Sponsors and ethics and regulatory committees.
- Provide cross cover to other established Trial Teams in the event of staff absences and assist the Research Lead with start-up activities on other newly funded trials, prior to the recruitment of trial staff.
- Work to Good Clinical Practice (GCP) guidelines on trial conduct and data management and ensure knowledge is kept updated.
- Follow established policies, procedures, objectives, continuous quality improvement objectives and the Norwich CTU Quality management System.

THE PERSON

EDUCATION, EXPERIENCE AND ACHIEVEMENTS

- A good standard of education with a minimum of five GCSEs including Mathematics and English or equivalent qualification or experience (E)
- Relevant degree or proven recent experience of working in a busy research or administrative role independently managing the implementation of tasks and systems (E)
- Experience of organising small and medium size meetings, liaising with participants and communicating agenda, background and minutes documents (E)
- Experience of maintaining filing systems with the ability to extract and supply information in support of senior colleagues (E)
- Experience of performing on-site or remote monitoring tasks on a clinical trial (D)

SKILLS AND KNOWLEDGE

- Excellent oral, written and interpersonal skills with ability to deal face-to-face, via telephone and email with individuals from a variety of backgrounds, culture and nationalities (E)
- Excellent organisational and time management skills with ability to prioritise competing

demands and priorities and meet deadlines (E)

- Excellent administrative skills (E)
- Excellent attention to detail (E)
- Good IT skills in Microsoft Office applications (E)
- Good presentation skills (E)
- Ability to generate accurate data/information from database record systems (E)
- Ability to produce work to a consistently high standard, within tight deadlines and to be able to handle confidential and sensitive information appropriately (E)
- Ability to plan and coordinate the communications for, and interactions on, research activities with collaborating sites (collaborating universities and others) (E)
- Ability to plan and arrange local travel for self and others (E)
- Familiarity with Good Clinical Practice (GCP) and/or with Information governance and data protection (E)
- Experience of supporting research, or delivery of a project or clinical trial and/or working in a clinical trials unit or clinical research organisation (E)
- Familiarity with LifeRay Content Management

System or other Content Management system for updating websites (D)

- General awareness of clinical research and current issues within the UK (D)
- Experience of clinical trial data collection principles and Case Report Forms (CRFs) (D)

PERSONAL ATTRIBUTES

- Self-motivated and able to work independently without close supervision (E)
- Able to work independently and as part of a team (E)
- Ability to promote best practice within the team (E)
- Well organised, methodical approach to work (E)
- Willingness to undertake appropriate training and apply knowledge learnt (E)
- Tenacity to follow actions through to completion (E)

Essential Requirements (E) are those, without which, a candidate would not be able to do the job.

Desirable Requirements (D) are those which would be useful for the post holder to possess and will be considered when more than one applicant meets the essential requirements.

THE PERSON (CONTINUED)

SPECIAL CIRCUMSTANCES

- Normal office hours although flexible working may occasionally be necessary (E)
- Willing to travel within the UK (E)

Essential Requirements (E) are those, without which, a candidate would not be able to do the job.

Desirable Requirements (D) are those which would be useful for the post holder to possess and will be considered when more than one applicant meets the essential requirements.

FURTHER INFORMATION

The post is available immediately on a fixed term basis for 12 months. There is a total of 1.5 FTE available and there is flexibility about how this is allocated.

We would consider appointments at a minimum of 0.5 FTE.

Salary will be £26,338 to £29,959 per annum, pro rata for part-time, on Grade 5 on the single salary spine.

Place of Work - The University is strongly committed to providing an excellent student experience and research environment, and it is expected that all staff will be available on campus to carry out their duties during their working week in support of these goals. We have a hybrid-working policy which supports a mix of at home and on campus 'hybrid' working for many roles. For the majority of hybrid roles, the expectation is a minimum of 60% of working time will be spent physically present in the workplace.

The flexibility of the hybrid-working policy allows the possibility of some remote working, but it is the expectation that all appointments will be UK based, with any overseas working agreed in advance by exception only.

If successful you will be asked to show evidence of right to work in the UK prior to any formal offer being made. Non-British and non-Irish nationals entering the UK to undertake employment or who are currently in the UK will have to meet eligibility criteria under the points-based immigration system. The University may be able to provide sponsorship under the Skilled Worker route if relevant criteria are met. Please note, due to the complexities of the immigration system, Skilled Worker visa sponsorship is not guaranteed for every role. If you would like further information about whether this role is eligible for visa sponsorship, please contact staff.visacompliance@uea.ac.uk

The post is superannuable under the Group Personal Pension and there is an annual holiday entitlement of 20 days plus statutory (8 days) and customary (6 days) holidays, pro rata for part-time. The University is committed to creating an environment where the health, welfare and safety of all students and staff is of paramount importance. The University's Safeguarding Policy addresses both child protection and safeguarding children, young people and vulnerable adults within the work of the

University. Appointment will be subject to satisfactory pre-employment checks, which may include an Occupational Health assessment.

Information on the benefits of working at UEA can be found at <https://www.uea.ac.uk/about/working-at-uea>.

If you require the information contained within this candidate brochure in a different format please email staff.recruitment@uea.ac.uk

HOW TO APPLY

To apply for this vacancy, please follow the online instructions at: <https://vacancies.uea.ac.uk>

The closing date for this role is 11:59pm on **Wednesday 2 April 2025**.

It is anticipated that interviews will take place on **Monday 28 April 2025** and we will inform you of the outcome of your application prior to this date.

Candidates should note that travel and incidental expenses incurred in attending an in-person interview will not be reimbursed.

ABOUT NORWICH MEDICAL SCHOOL

Norwich Medical School (MED) was established at UEA in 2001 and has over 200 members of academic, research and support staff – and a large number of active NHS secondees and honorary appointees from a wide range of disciplines (including medical specialties, clinical psychology and psychological therapies, biological sciences, health economics, epidemiology and medical statistics). In our relatively short history we have established a reputation for exciting and innovative research led teaching supported by a wide-ranging programme of research and team science.

The School has grown significantly with increases in the number of MB BS students as part of the national requirement to increase junior doctor numbers. The School also delivers a large number of Post Graduate programmes which support the NHS workforce, including ClinPsyD, IAPT, EMHP and CAP hosted within a thriving Department of Clinical Psychology and Psychological Therapies which has more than doubled in size. The School also includes a highly regarded Doctoral School supported by the Universities Doctoral College.

The School's research focus is on developing translational research themes that answer important health questions, from an understanding of the basic mechanisms and genetics of disease through mental and psychological health to clinical trials

and from there to incorporation into clinical guidelines and evaluation within the broader health care community.

We benefit from being a core part of Norwich Research Park (NRP), which has over 3000 scientists who predominately carry out translational health-related research. NRP includes three BBSRC supported institutes - the Quadram Institute the John Innes Centre and the Earlham Institute, as well as the NNUH. The proximity of NRP partners facilitates close working relationships and cross-fertilisation of research ideas. In addition to the NNUH, the medical school enjoys a strategic partnership with other teaching Trusts: the James Paget University Hospital in Great Yarmouth, Norfolk and Suffolk Foundation NHS Trust in Norwich, Ipswich Hospital and the Queen Elizabeth Hospital, Kings Lynn as well as local Clinical Commissioning Groups (CCGs).

Further information on the School can be found at <https://www.uea.ac.uk/about/norwich-medical-school>



ABOUT THE FACULTY

The Faculty of Medicine and Health Sciences (FMH) is a vibrant community of students and staff engaged in education, continuing professional development, research and enterprise, led by the Pro Vice Chancellor of Medicine and Health Sciences, Professor Charles French-Constant. Our primary focus is on supporting our regional, national and international partners in Health by delivering outstanding education and innovative research.

Teaching is undertaken from Undergraduate, including apprenticeships, through to Postgraduate and Post-Doctoral education and further training through the Faculty's two Schools of study, comprising Health Sciences (HSC) and Norwich Medical School (MED) incorporating Clinical Psychology and Psychological Therapies (CPPT), assisted by the Centre for Inter-professional Practice (CIPP).

The Faculty is engaged in world leading research across four centres: Biomedicine and Mental Health, Healthy Aging, Epidemiology & Health Evaluation, Health and Care Innovation. The centres drive forward research aimed at restoring, sustaining and evaluating health and we have internationally recognised research expertise in cancer, cardiovascular and metabolic disease, psychological health, healthy aging lifestyle and diet, epidemiology, public health, clinical trials, health economics

and care research. We have strong links with the Norwich Research Park, comprising the Quadram Institute (QI), the John Innes Centre (JIC), the Earlham Institute (EI) and the Norfolk and Norwich University Hospital NHS Foundation Trust. We are also linked to a wide range of other Health Partners through our Health and Social Care Partners' team and the Citizens Academy, see [http:// www.worldclassnorfolk.com/work/future-science](http://www.worldclassnorfolk.com/work/future-science).

We provide an engaging, collegiate and supportive environment for all of our staff and students. This fosters a culture of compassion and academic rigour which delivers opportunity for inspirational roles in a sector that is pivotal to the Health and Wellbeing of those living in our local area, whilst having national and international impact.

Under the recent Research Excellence Framework (REF2021), FMH performed strongly, with our outputs ranking equal 5th for Clinical Medicine, 11th for Allied Health Professions, Dentistry, Nursing & Pharmacy, and 11th for Psychology, Psychiatry and Neuroscience. Our food researchers were ranked equal 2nd for outputs and equal 1st overall in the UK. UEA overall also made strong gains, ranking 20th of 167 research active Universities in the UK, and 16th overall for the impact of our research.



OUR VALUES

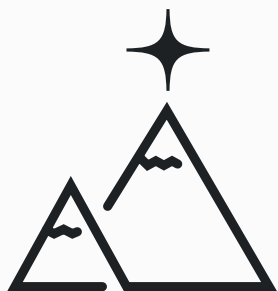
Shaped by staff, our UEA values represent a core set of standards for how we behave as an employer, drive excellence in teaching, learning and research, and collaborate as an anchor institution in our local community.

From tackling global challenges, striving for student and staff success, and creating a vibrant inclusive environment, our values are what unite us.

- ✦ AMBITION
- ✦ COLLABORATION
- ✦ EMPOWERMENT
- ✦ RESPECT



OUR VALUES (CONTINUED)



AMBITION

We are ambitious for our future success.

We are forward-thinking and brave in our approach and decisions. We make space for innovation and creativity, seizing opportunities that are responsible and sustainable. We are ambitious for the advancement of education and research.



COLLABORATION

We are collaborative in our approach.

We work together with shared purpose. We build connections, share ideas and develop new networks. We champion our regional, national and global relationships and demonstrate that together we can achieve greater goals and positively influence the world around us.



EMPOWERMENT

We empower ourselves and each other.

We develop ourselves and others, trusting people to make decisions based on their expertise and knowledge. We continually improve systems and processes to support us in working in an agile and efficient way.



RESPECT

We respect each other.

We treat everyone with respect and dignity. We value diversity and foster a community where people can express different thoughts and views. We are open to challenge, so we can learn and improve. We encourage a positive, inclusive environment where everyone has opportunities to fulfil their potential.

ACCOLADES

- Queen's Anniversary Prizes for Higher and Further Education have been awarded to UEA for international development studies (2009), creative writing (2011) and environmental sciences (2017). Notable alumni include Sir Paul Nurse (1973, Nobel Prize for Medicine 2001), Kazuo Ishiguro (1980, Nobel Prize for Literature 2017), Michael Houghton (1972, Nobel Prize for Medicine 2020) and Sarah Gilbert (1983) who led the Oxford University team to develop a COVID-19 vaccine, approved in 2020.
- Our Doctoral College, established in 2018, hosts six Doctoral Training Partnerships and integrates Faculty and School provision for 1600 Postgraduate Research Students (including those from across the Norwich Research Park), enabling collaboration and innovation.
- We recognise our global impact and were one of the first universities to declare a climate and biodiversity emergency in June 2019. Our sustainable campus, including over 50 acres of environmentally valuable parkland, is constantly evolving with ambitions to be 100% net zero by 2045 or sooner.
- UEA is a University of Sanctuary, an accreditation given to universities that show an ongoing commitment to creating a welcoming culture of inclusivity and awareness.
- UEA was awarded the Silver Athena SWAN Award in 2019, and all our Schools hold awards at Bronze or Silver.

A vibrant place to study, learn and work, UEA is a very special place.



A SUSTAINABLE UNIVERSITY

At UEA, we are now working to create a university that will be even better in the future, and we are working to achieve net zero carbon by 2045 (or earlier). Our Sustainable Ways vision is one of a resilient university – where consumption is efficient and self-generated energy supports low carbon goals, supported by a vibrant community of world-leading researchers and inspired graduates.

At a basic level, our sustainable development means that we try to balance the ‘three pillars’ of environmental, economic and social elements.

We challenge our environmental impact through on-site energy generation and a district heating and cooling network, reducing our reliance on grid electricity and therefore fossil fuels. We promote and use recycled and ‘eco’ products such as biological cleaning materials. We champion local suppliers and ethical causes, including Fairtrade and vegan products. We seek to ensure value for money in a holistic, whole-life costing sense in our new buildings and procurement contracts.

OUR INITIATIVES

Central campaigns, such as holiday shut-downs or awareness day events, support a whole-University approach to energy saving and other initiatives.

Follow us on Twitter [@SustainableUEA](https://twitter.com/SustainableUEA)



OUR CAMPUS

UEA is based on a campus that provides top quality academic, social and cultural facilities to over 17,000 students.

Although located in 320 acres of rolling parkland, virtually no part of the campus is more than a few minutes' walk from anywhere else, so everything is close at hand – the library, nursery, health centre, supermarket (incorporating a post office), banking facilities and restaurants. Amongst the striking buildings is the UEA's Sainsbury Centre for Visual Arts, which contains the Robert and Lisa Sainsbury Collection – one of the greatest art collections formed in Europe during the 20th Century.

The University has invested in new learning and teaching and research spaces, including a celebrated new Enterprise Centre that underpins its commitment to promoting student enterprise and entrepreneurship.

Sport and Recreation plays a major part in the life of the University of East Anglia, centred around the major Sportspark facility which is one of the most successful community sport facilities in the UK. This accessible and affordable facility provides a diverse range of activities, and incorporates a 50m Olympic size swimming pool, indoor climbing wall, coaching resource centre and sports injury clinic.



NORWICH

A CITY OF STORIES

The city's motto is 'A fine city' and its strong cultural heritage has seen Norwich maintain the best of its historical character whilst developing to become one of the most vibrant and attractive cities in Europe. Norwich offers miles of riverside walks and cycle ways, and a unique collection of 1930's parks. The city is surrounded by beautiful countryside and within easy reach of the stunning Norfolk coast.

Norwich is a UNESCO World city of Literature, the first in the UK, as well as being one of the newly named Tech Cities recognising the growth of digital businesses in the region. The most prominent high-rise building, apart from the castle, is the magnificent 11th century cathedral, which still dominates the skyline. The city's medieval centre of cobbled streets remains largely intact, but there is still space for modern buildings such as the city's centrepiece, the Forum, which is a striking piece of contemporary architecture. The glass front overlooks the colourful open-air market (one of the largest in the country) and reflects the city in all its diversity.

The city is consistently rated as one of the top ten shopping venues in the UK. Norfolk and Suffolk attract thousands of visitors each summer. The famous Norfolk Broads are among the most important wetlands in Europe and a haven for rare plants, wildlife and insects. The Broads attract holidaymakers who come to navigate the intricate natural network of waterways formed by the Rivers Bure, Yare and Waveney and their tributaries.

For further information about UEA's excellent facilities, staff benefits, picturesque campus and the UEA working environment, please visit the 'Careers at UEA' microsite <https://www.uea.ac.uk/about/working-at-uea>. Additional information about living and working in the city of Norwich can be found at <https://www.workinnorwich.co.uk/>



If there is another city in the United Kingdom with a school of painters named after it, a matchless modern art gallery, a university with a reputation for literary excellence which can boast Booker Prize-winning alumni, one of the grandest Romanesque cathedrals in the world, an extraordinary new state-of-the-art public library then I have yet to hear of it. Norwich is a fine city. None finer.

STEPHEN FRY



LOCATION

Some cities you've heard of, others you have to discover. Norwich is one of the most beautiful, modern historic cities in Britain. It's a city that celebrates the independent, stimulates creativity, promotes change and encourages diversity.

UEA is a campus university located 3 miles from the centre of Norwich. Situated in the heart of Norfolk, which means it's an ideal location to explore Norwich and beyond.

BY RAIL

LONDON • 2 HOURS

CAMBRIDGE • 1 HR 15 MINS

BIRMINGHAM • 4 HOURS

Many European cities (including Paris and Amsterdam) easily accessible by train

BY ROAD

KINGS LYNN • 1 HOUR

CROMER • 45 MINUTES

SOUTHWOLD • 1 HOUR

BY AIR

NORWICH AIRPORT • 20 MINUTES

STANSTED AIRPORT • 2 HOURS

London is a major airline hub and all main international destinations are easily accessible



An internationally renowned university, UEA is ranked in the UK Top 25 (Complete University Guide 2025), UK Top 30 (The Mail 2025) and the World Top 100 (Times Higher Education Impact Rankings 2024), where it ranks in the UK Top 20 for research quality (Times Higher Education Rankings for the Research Excellence Framework 2021) and World Top 20 for Health and Wellbeing (QS World University Rankings for Sustainability 2024), reflecting the international excellence of its research environment. The University holds UK Teaching Excellence Framework Silver status.

Equality, Diversity, Inclusion and Wellbeing

The University is committed to diversifying its workforce and to the wellbeing of all our staff. For example, we already hold an Athena Swan Silver Institutional Award in recognition of our advancement towards gender equality. Further details on our broader Equality, Diversity, Inclusion and Wellbeing work can be found on our [website](#).

