



University of
Southampton



BE PART OF OUR SUCCESS

**JOIN OUR REMARKABLE TEAM AS THE HEAD OF
DATA MANAGEMENT AND INFORMATION SYSTEMS
AT THE SOUTHAMPTON CLINICAL TRIALS UNIT**

FOREWORD

Thank you for your interest in the position of Head of Data Management (DM) and Information Systems (IS) at the Southampton Clinical Trials Unit.

The need for internationally excellent, research-intensive universities like Southampton to help tackle some of the world's biggest challenges has never been more important and urgent than it is now. At the Southampton Clinical Trials Unit, our aim is to constantly improve patient care by helping to develop the treatments and medical interventions of the future. We work with researchers and clinicians across the UK and internationally to design, conduct and publish world-leading and life changing clinical trials and other well-designed studies. We are focused on having a truly collaborative, innovative and ground-breaking impact. We care passionately about the challenges that patients and the NHS are facing and are working to improve health care on both a UK and global scale. Join us in this work, and you will have the opportunity to make a tangible difference to future generations.

The Southampton Clinical Trials Unit is both Cancer Research UK (CRUK) core funded and National Institute for Health and Care Research (NIHR) support funded, and is a fully UKCRC registered CTU sitting within the Faculty of Medicine at Southampton General Hospital. The Head of DM and IS role is part of the senior management team and will contribute to achieving these bold ambitions and helping us to thrive in this changing environment. It will play an important part in championing the new University Strategy and the strategic research aims of Cancer Research UK, NIHR and our NHS partners (such as University Hospital Southampton NHS Foundation Trust).

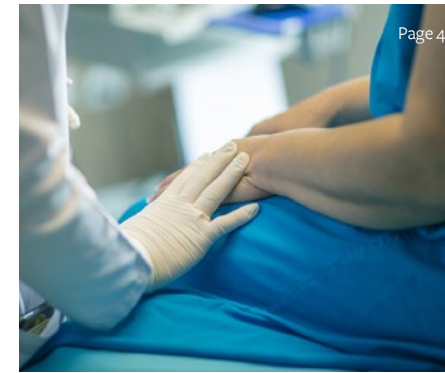
The impact of the worldwide COVID-19 pandemic required us to reaffirm what matters most as a diverse community and to develop a strategy that enabled us to emerge from it strongly and safely. The University's strategy, with people at its heart, encapsulates the Triple Helix of excellence that is research-education-knowledge exchange and enterprise, which aims to make the Southampton offer distinctive.

The University of Southampton is already known as a founding member of both the UK's prestigious Russell Group of leading research-intensive universities and the Worldwide Universities Network (WUN). With campus operations in Malaysia and China, as well as major partnerships across the world, we have a global outlook that attracts the most talented staff and students from around the world.

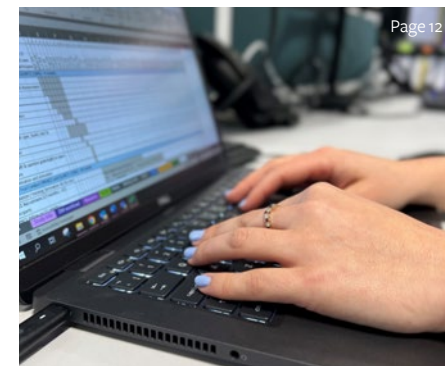
If you want to take your career to new heights, and believe you have the skills, experience and drive to help lead the data management team at the Southampton Clinical Trials Unit, we want to hear from you. If you can help the Unit deliver its current objectives and develop a forward-facing and impactful vision and strategy for the data team that is aligned with our strategic priorities, objectives, we look forward to receiving your application.

It is important that we find the right person for this role, whatever their circumstances. We will endeavour to be as flexible as possible to consider individual requirements and circumstances to find the optimum solution for the successful applicant.

Please see page 8 for more information on equality, diversity and inclusion.



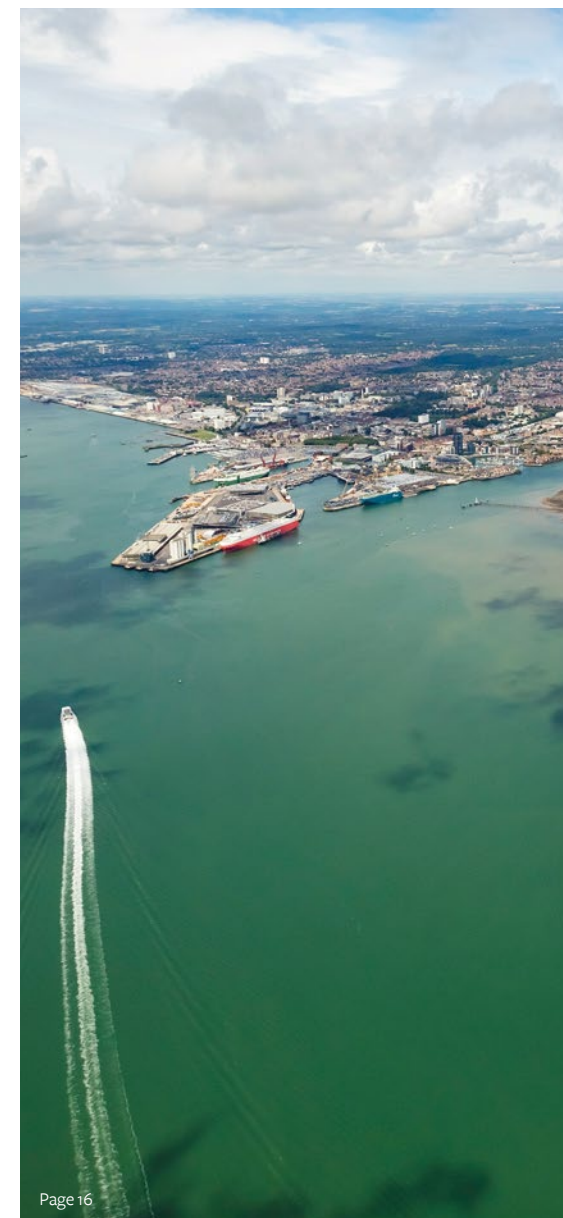
Page 4



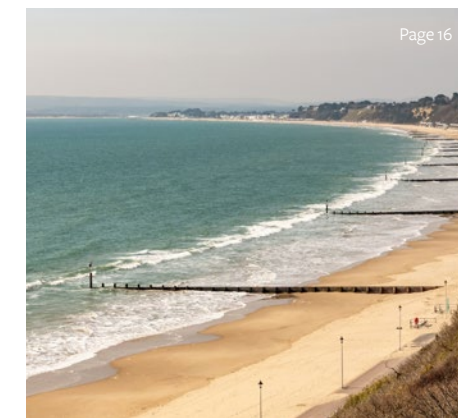
Page 12



Page 6



Page 16



Page 16



Page 16



Page 16

Together we advance

Working collaboratively to make a real impact on patient benefit.

Page 4

Our values

Activities underpinned by the values determined by our University community.

Page 6

Equality, diversity and inclusion

It matters to us in all that we do.

Page 8

Overview of the role

Head of Data Management and Information Systems

Page 10

The role

Job description and candidate profile.

Page 12

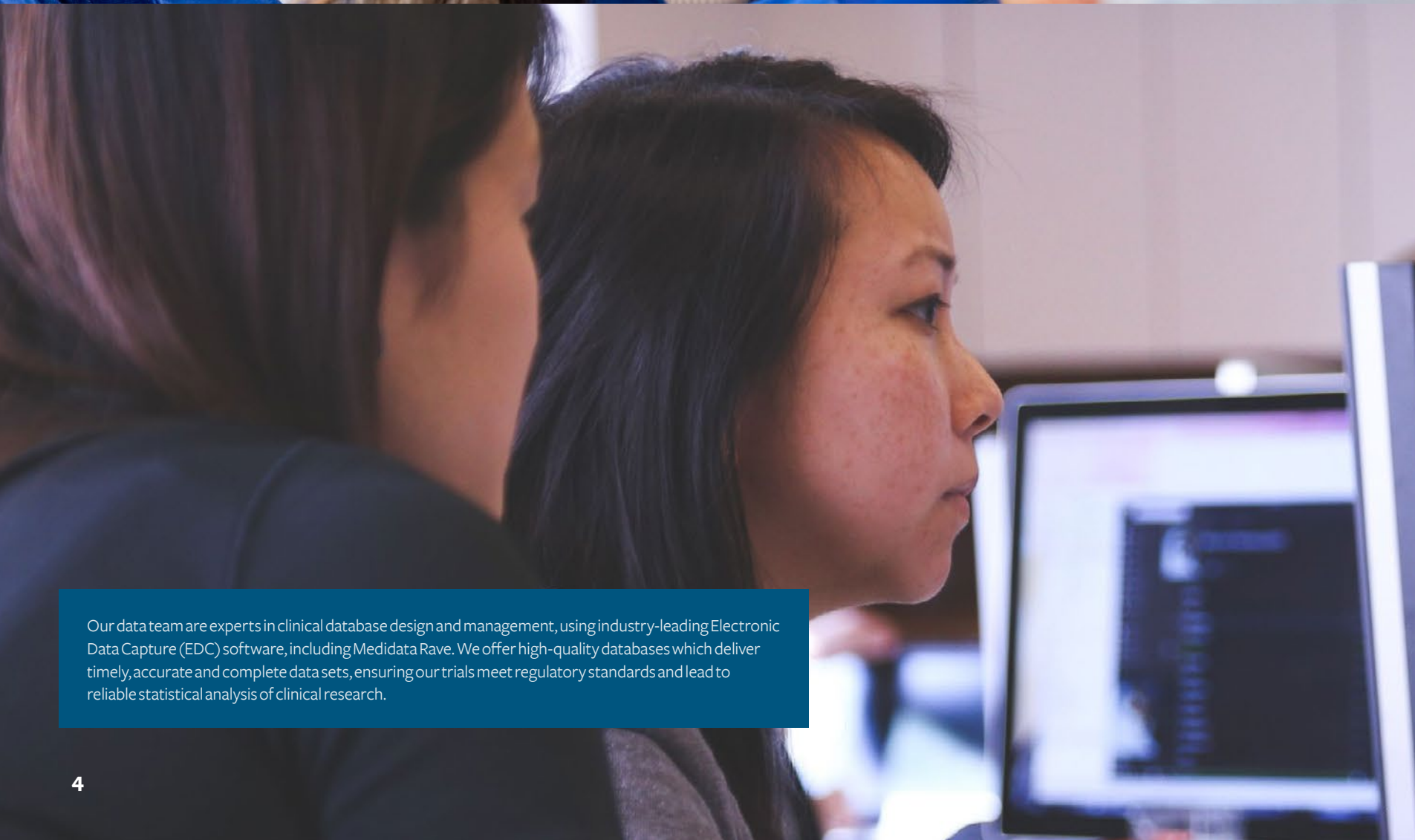
Location

The Southampton Clinical Trials Unit, University and region.

Page 16



Southampton Clinical Trial Unit (SCTU) is a Cancer Research UK core funded and UKCRC registered CTU which designs, initiates, conducts and analyses high quality national and international academically sponsored clinical trials and other well-designed studies to directly influence and change routine clinical practice. The SCTU study portfolio includes phase I (first-in-human) to phase 3 clinical trials, complex intervention mixed-methodology studies, observational studies (including large, cancer early diagnosis, community-based studies) and translational studies.



Our data team are experts in clinical database design and management, using industry-leading Electronic Data Capture (EDC) software, including Medidata Rave. We offer high-quality databases which deliver timely, accurate and complete data sets, ensuring our trials meet regulatory standards and lead to reliable statistical analysis of clinical research.

TOGETHER WE ADVANCE

Together we can make a real impact on the future.

Our University community is committed to the highest quality in everything we do. We have a global reputation for our passion and ability to work collaboratively in delivering world-class education, research and innovation that makes a real impact on society's biggest challenges.

To meet those challenges head-on, we must have a team that is reflective of society and our students. We strive for greater inclusivity in our community. Diversity is a strength and makes us more creative, accelerating our impact on society. We celebrate an equal and respectful environment in which people from all walks of life and backgrounds are welcome to join us.

Our people inspire and empower one another to share and apply their knowledge to transform lives. They are key to what we do, and who we are. Working collaboratively and fostering a culture of transformational leadership are two of our five core values. These values form part of our new University Strategy and are there to help us achieve our overall purpose and vision: to inspire excellence, to achieve the remarkable, and build an inclusive world. Find out more about our values on page 6.

Our people are our University, which is why our Strategy and all of our activities focus on the communities that make up our institution. We are made up of brilliant minds, motivated leaders and passionate changemakers. By working collaboratively, we can achieve incredible things.

Our exceptional students share in the journeys of discovery and become confident thinkers who can realise their full potential. We attract high-quality students from over 130 countries, and educate students through University of Southampton Malaysia and collaborations with prestigious partners globally.

As our students become graduates of the University, they join our wider global community of over 265,000 alumni, with access to a network that can provide further opportunities across the world.

As a forward-thinking institution, we will strengthen our reputation, increasing our national and international rankings to secure a position in the top 10 in the UK and strengthen our position in the top 100 internationally.

Our strong research partnerships, public engagement and achievements in entrepreneurial activities have been recognised in our very strong all-round performance in the first Knowledge Exchange Framework (KEF) exercise.

Work with us: together we advance.

 **Find out more**
The University Strategy

OUR VALUES

Our values provide the lens through which we make decisions, guiding our actions, collective behaviours and systems.

They are integral to our purpose of building an inclusive community that makes positive change.

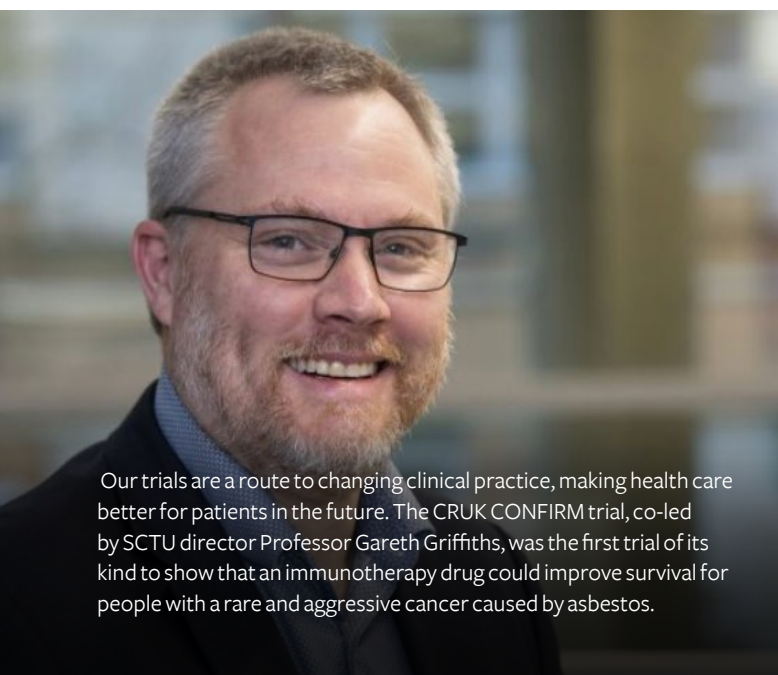
We are ambitious: both personally and institutionally, which requires us to be collaborative and collegial.

As a community of talented individuals, our systems need to enable and empower us. Our community upholds academic freedom and develops through constructive, civil debate.

Ensuring different views are heard allows us to make the best decisions.



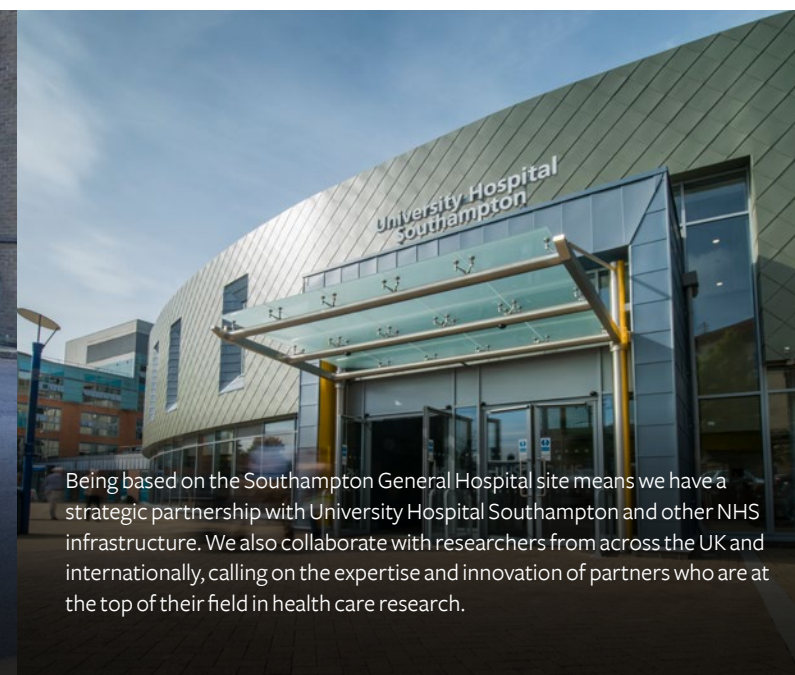
Our values in action



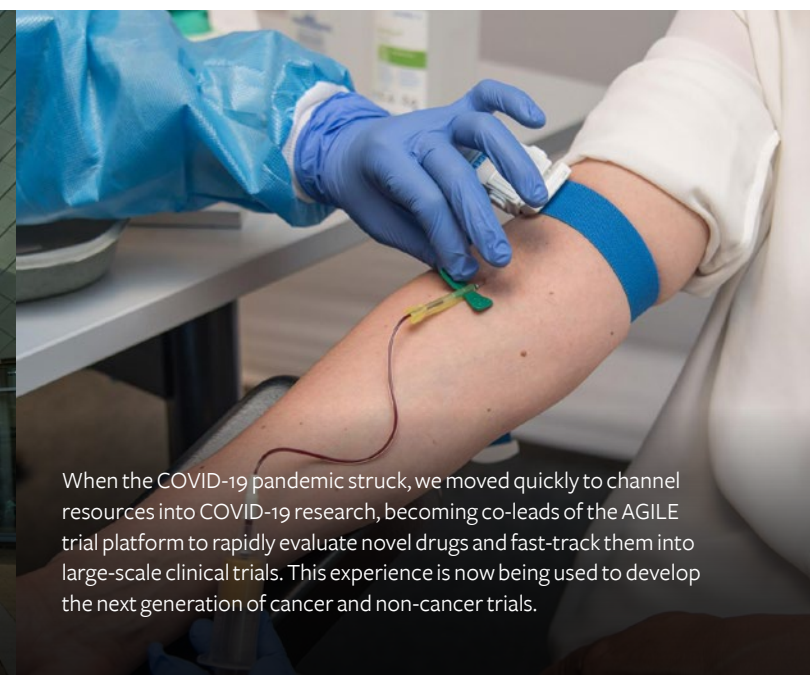
Our trials are a route to changing clinical practice, making health care better for patients in the future. The CRUK CONFIRM trial, co-led by SCTU director Professor Gareth Griffiths, was the first trial of its kind to show that an immunotherapy drug could improve survival for people with a rare and aggressive cancer caused by asbestos.



Our innovative iDx Lung trial takes research out into the community, reaching wider populations and increasing accessibility for trial participants. Partnering with the NHS and biotech companies, we're trialling new tools to diagnose lung cancer in its early stages.

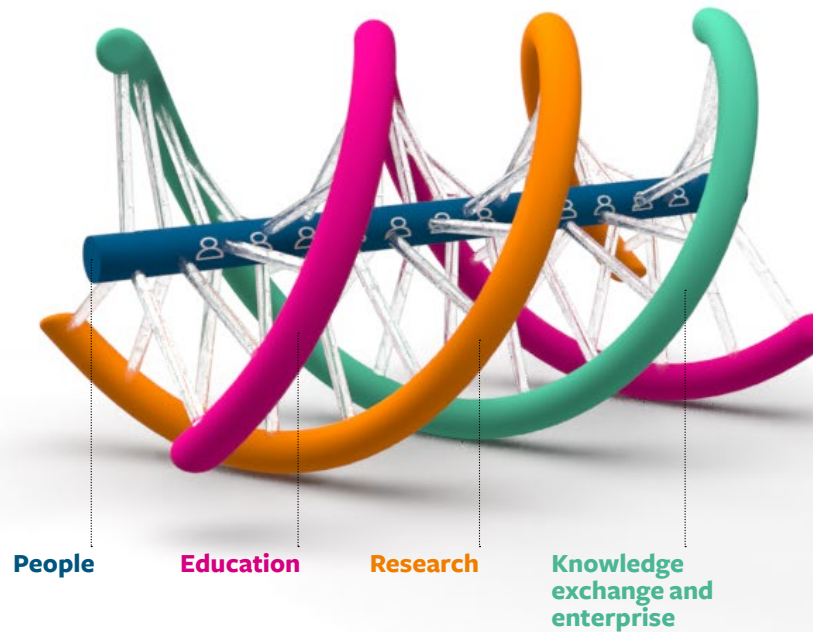


Being based on the Southampton General Hospital site means we have a strategic partnership with University Hospital Southampton and other NHS infrastructure. We also collaborate with researchers from across the UK and internationally, calling on the expertise and innovation of partners who are at the top of their field in health care research.



When the COVID-19 pandemic struck, we moved quickly to channel resources into COVID-19 research, becoming co-leads of the AGILE trial platform to rapidly evaluate novel drugs and fast-track them into large-scale clinical trials. This experience is now being used to develop the next generation of cancer and non-cancer trials.

People are at the core of our Triple Helix



Our highly-ranked **education, research and knowledge exchange and enterprise (KEE)** are already distinctively intertwined.

By strengthening and increasing these links, our Triple Helix approach will achieve greater impact and accelerate new ways to tackle the world's most complex problems.

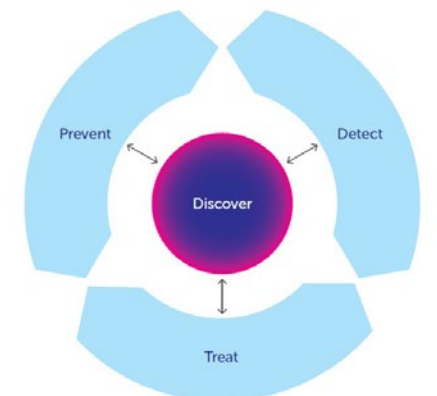
This scaling up is a challenging goal we commit to achieve; its reach and ambition sets us apart.

OUR RESEARCH OBJECTIVES



We fund world-class research to tackle the burden of cancer through the delivery of four objectives: discover, prevent, detect and treat. These objectives are not isolated from one another; they form a virtuous cycle where deeper understanding of every aspect of cancer ultimately leads to longer, healthier lives.

- Discover:** We will understand the mechanisms of how cancer develops and progresses to unlock new and better ways to prevent, detect and treat it
- Prevent:** We will use biological insights to inform a new wave of preventive interventions that decrease cancer incidence equitably across society
- Detect:** We will detect cancer at the earliest point of intervention by understanding the underlying biology of cancers and the transition from health to early disease
- Treat:** We will use biological discoveries about the mechanisms of how cancer evolves to inform clinical studies



EQUALITY, DIVERSITY AND INCLUSION

It matters to us in all that we do.

At the University of Southampton, we believe that we can only truly play our part in supporting society if we are reflective of society. We are therefore passionate about creating a working environment in which you are free to bring your whole self to work.

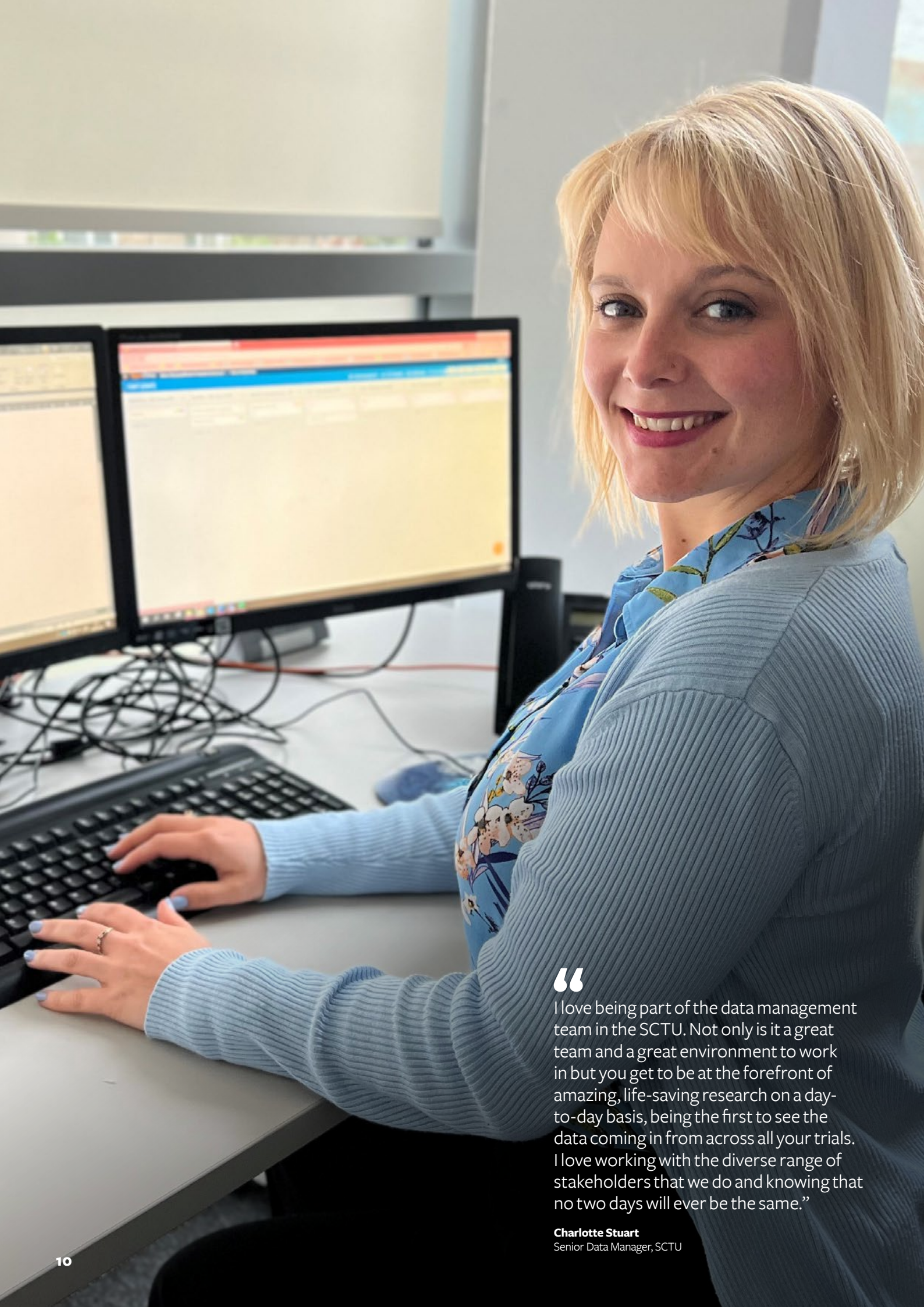
We are focused on creating supportive workplaces for all where discrimination has no place. The way in which you choose to live your life has no bearing on your ability to do your job. Likewise, your age, gender, sexual orientation, religion, social background, ethnicity or any other identifying factor will never be a consideration here. Instead, we are determined to always treat our staff equally, fairly and with respect.

We welcome people from all walks of life, and as such, we champion a uniquely diverse working environment in which every colleague is able to excel, regardless of their background or their life choices. Quite simply, we want to attract likeminded people to our team – people who care about the world, and who share our passion for creating an innovative and forward-thinking learning and research environment.

We are proud to support many staff networks, and we encourage these groups to get involved in helping us create a forward-thinking and desirable workplace. We are a Stonewall Diversity Champion and we are immensely proud to have been awarded an institutional Athena SWAN silver award, which underpins our pledge to improve equality for women.

We also support flexible working and are proud of our open and supportive working environment; with options such as job shares available, we ensure opportunities are equal and focused on the needs of our colleagues. We know that change and improvement is a continual process, and our community is a big part of this, so we always want to hear from our staff about how we can create the best possible working experience.





“

I love being part of the data management team in the SCTU. Not only is it a great team and a great environment to work in but you get to be at the forefront of amazing, life-saving research on a day-to-day basis, being the first to see the data coming in from across all your trials. I love working with the diverse range of stakeholders that we do and knowing that no two days will ever be the same.”

Charlotte Stuart
Senior Data Manager, SCTU

HEAD OF DATA MANAGEMENT AND INFORMATION SYSTEMS

The Southampton Clinical Trials Unit (SCTU) is a world leading Clinical Trials Unit with nearly 100 staff members and a large portfolio of trials which cover the complete spectrum of clinical practice from primary care through to tertiary referral medicine, including cancer care, experimental therapeutics, surgery, supportive care and prevention. Undertaking multi-centre early and late phase clinical trials, we work nationally and internationally to create the evidence for patient benefit that will directly influence routine clinical practice in the NHS and overseas. SCTU has expertise in the design, conduct and publication of multicentre, interventional clinical trials and other well-designed studies. This is a rare and exciting opportunity to join our senior team as the Head of Data Management and Information Systems and be a part of a life changing journey for patients.

This role will see you lead a well-established team of 20, which includes Senior Clinical Data Programmers, Senior Clinical Data Managers, Clinical Data Programmers, Clinical Data Managers, Clinical Data Co-Ordinators and Data Assistants with a reputation for clinical data excellence and a vast experience of working with site teams and industry partners to ensure the integrity and authenticity of trial data.

You will join an experienced leadership team with a passion to drive the unit forward and cement our position as one of the leading CTUs in the UK and to establish ourselves as a world leading CTU.

As an employee of the University of Southampton you will enjoy a competitive salary and a generous benefits package which includes:

- A generous holiday entitlement, including bank holidays and university closure days per year.
- Qualification for the USS pension scheme, with large employer contributions to your pension.
- Employee benefits such as the access to the Cycle to Work Scheme, the new Low Emissions Car Scheme, and University discounts at hundreds of shops, services and businesses across the south.
- You will work in close consultation with the SCTU Director, Associate Directors and senior leadership team.

The Southampton Clinical Trials Unit is a UKCRC registered CTU and is Cancer Research UK (CRUK) core-funded. We are located within the state-of-the-art Centre for Cancer Immunology building at Southampton General Hospital.

As part of the NIHR and CRUK infrastructure we have close working relationships with our partners, including the Southampton CRUK Centre and Experimental Cancer Research Centre and NIHR partners across Wessex such as the NIHR Research Design Service, NIHR Clinical Research Network, Clinical Research Facility, Biomedical Research Centre, the Wessex Institute and University Hospital Southampton.

How to apply

For a conversation in confidence or details of how to apply, please contact

Peta Durrant, Head of Operations
P.A.S.Durrant@soton.ac.uk

For details of how to apply for this role and the closing date, please visit
<https://jobs.soton.ac.uk/Vacancies.aspx>

HEAD OF DATA MANAGEMENT AND INFORMATION SYSTEMS

Job purpose

Southampton Clinical Trial Unit (SCTU) is a Cancer Research UK core funded and UKCRC registered CTU which designs, initiates, conducts and analyses high quality national and international clinical trials and other well-designed studies to directly influence and better routine clinical practice. The SCTU study portfolio includes phase I (first-in-human) to phase 3 clinical trials, complex intervention mixed-methodology studies, observations studies (including large cancer early diagnosis community-based studies) and translational studies.

The role requires the successful candidate to lead the Data, Management (DM) group within SCTU, providing leadership and direction for the development and continued improvement of data governance, data management services (e.g. RAVE and other solutions), utilizing routine NHS data into trials, digital solutions (e.g. e-Trial Master File [eTMF], e-Patient Reported Outcomes [e-PROs], e-CONSENT, Clinical Trial Management Systems [CTMS], Secure Data Environment [SDE]), and the strategic direction for DM and SCTU information systems (in line with the broader SCTU strategic plan and in support of the Director)

Key accountabilities/primary responsibilities

Strategic leadership

- To provide senior professional leadership for the data management team (including data manager and database programmer staff). Manage the prioritisation, with the steer from the Director and Head of Operations, of activities within the Data Management Function.
- To lead on data management, data protection, data sharing processes, data lifecycle management (including storage and final repository) on behalf of the SCTU and other stakeholders as appropriate. Ensure necessary strategies and process in place for data curation, stewardship, performance reporting of sites etc and e-archiving of electronic data.
- Act as an advisor for complex or new data issues relevant to the design of new clinical trials and other well-designed studies through to end of study and on-going data release. Scope and steer SCTU in improved practice with regard to technological tools including CTMS, e-PRO, sample tracking systems and the sharing and storing of trial data (with associated omic, image and routine NHS data linkage) using secure data environments (SDE) and other databases storing translational assets, in close collaboration with other SCTU groups, including but not limited to, trial management, statistics, translational and bioinformatics.
- To chair data sharing meetings and act as an advisor with regards to data sharing and SDE access within SCTU. Input into protocols with regards to the data management and sharing aspects. Assist the SCTU with regards to review of data sharing clauses in contracts and ensuring compliance with such clauses. Assisting and supporting staff where DPIAs are required.

- To identify and lead initiatives relevant to data management and information system solutions within SCTU (and as requested across the UK Clinical Trial Unit network (Cancer Research UK/UKCRC)) to improve current practice by ensuring data management and other digital solution provision is fit for purpose, flexible, efficient, competitive and meets the varied needs of the SCTU portfolio (including the ability for hybrid working of all SCTU staff).

Strategic development

- To maintain an excellent knowledge of regulatory requirements for clinical trials data management systems and digital technology, to ensure SCTU processes are regulatory compliant.
- Develop, produce and maintain SOPs, quality systems and clinical audit of research activity, and adhere to all SCTU and University policies and procedures.
- Ensure the effective management of relevant financial activities regarding digital technology solutions and data management functions across the SCTU, including input to bids for further grant incomes. To be the business lead for procurement for any requests/tenders/negotiations regards data management and digital technology solutions.
- Assisting with due diligence of new e/digital suppliers. To ensure that there is good vendor selection and oversight of new systems implemented by SCTU. To work with the University Finance and the Procurement teams to ensure we follow the correct Public Procurement and UoS processes.

Line management and performance responsibilities

Managing People: Manage and support your people's work productivity, performance, wellbeing and development to maximise their contribution and enable personal growth.

- To line manage and mentor the data management team, ensuring effective resource strategies and allocation.
- To set training standards and required competencies for staff and act as an accessible resource to support delivery as and when required by the SCTU.

Internal and external relationships

- Take a leading role in discussion with industry and international partners for database requirements when developing collaborative academically sponsored studies.
- Represent and promote SCTU at an international, national and local level; with contributions that make a difference, at relevant working group meetings and conferences.
- Liaise with other staff within Southampton Clinical Trials Unit, including but not limited to the Directorship committee, operations, trial management, QA/PV, statistics, translational and bioinformatics.
- Maintain relationships with the UHS and UoS sponsorship office (or other sponsors of SCTU trials as appropriate) and other external stakeholders, including other Clinical Trials Units CRUK, NIHR, and other funders.
- Maintain relationships with UHS and UoS Clinical Informatics Research Unit and other external database providers in the development of a SCTU SDE External software and digital technology.

CANDIDATE PROFILE

Qualifications, knowledge and experience

Essential:

- BSc Hons and proven level of expertise in the fields of clinical operations, data management and associated digital technology.
- Proven management skills in the specialist field of clinical operation systems, data governance, data stewardship, the data management lifecycle, data management etc.
- Knowledge in ICH GCP and regulatory landscape relevant to digital platforms
- Experience in leadership.

Desirable:

- Expertise in Medidata Rave (or equivalent) and secure data environments or other associated data management platforms.
- Knowledge of various systems for randomisation.
- Previously worked in a UKCRC Clinical Trials Unit or equivalent.
- Understanding of industry data standards for licencing

Planning and organising

Essential:

- Able to plan and shape the direction of the DM group and information governance on behalf of the SCTU.
- Proven experience of managing significant change and organising major new changes, such as vendor management and implementation of new platforms and technology for data curation, electronic data capture, mobile health and digital solutions, executing relevant due diligence.

Problem solving and initiative

Essential:

- Able to develop solutions and solve problems under own initiative in order to ensure the DM group continues to provide a flexible and fit for purpose service across the entire SCTU portfolio.

Management and teamwork

- Able to proactively develop team dynamics and performance, ensuring quality standards are consistently achieved.
- Able to foster positive relationships both within and outside of the SCTU with key stakeholders.
- Able to proactively work with senior peer group within the SCTU to achieve key deliverables in line with the SCTU overarching strategic vision.

Communicating and influencing

Essential:

- Able to negotiate effectively on behalf of the SCTU on key issues.
- Able to effectively communicate with the Data Management Team and other senior managers and Directors within SCTU.
- Able to develop and lead key communications strategies as required and in line with the SCTU overarching strategic vision.

Other skills and behaviours

Essential:

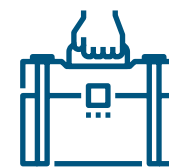
- Strong team player able to demonstrate an ethos of support for delivery for the strategic vision of the SCTU.
- Experience in the tender process and the grant application process.
- Experience managing budgets

Special requirements

- Travel to external meetings will be required on an ad-hoc basis.

In the SCTU data team we pride ourselves in the expert service we provide, from the scoping stages of database builds through to database freeze and lock. Our expanding portfolio of disease areas provides a rich catalogue of experience from which we draw on to help support both CRF and ePRO development. Our CDASH-compliant global library of commonly used, validated CRFs are constantly growing, providing a foundation of quality and efficiency. During study conduct we work closely with sites to ensure data is entered timely and accurately. Overall, our experience is wide ranging both in terms of trial designs and with the types of stakeholders we collaborate with.

Southampton
is ranked
78th
in the world¹



Received
£114.7m
in research grant and
contracts income
in 2021/22²



92%
of our research has been
classed as world leading or
internationally excellent³



Engaged in
research with over
700
overseas partners



We attract high-
quality students
from over 130
countries



Overall student satisfaction at
Southampton is **significantly
ahead of the sector** and is a
strong performance against our
competitor set, the Russell Group,
and the sector⁴



A founding member of
the Russell Group of 24
major research-intensive
universities in the UK



Founding member
of the Worldwide
Universities Network

We have over
24,000
students, including
more than
9,000
international students



£4.14bn
of economic
impact across
the UK in
2020/21⁷



**Ranked
13th**
in the UK⁵

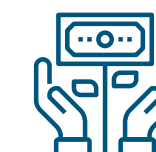
Our 265,000 alumni
community spans
over

190
countries

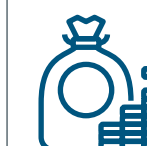


We employ over 6,500 staff

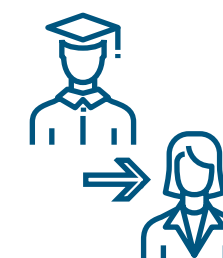
Very strong
performance in the first
KEF exercise⁶



Over the next decade,
we plan to invest over
£300m
in our infrastructure
and facilities



Our income
exceeded
£673m in
the 2021/22
financial year²



Our partnership with Lloyd's
Register represents the
largest university-business
collaboration of
its kind in the UK



At any one time we are
working with over
1,000
external organisations
around the globe

¹ QS World University Rankings, 2023

² University of Southampton Financial Report, 2021/22

³ Research Excellence Framework, 2021

⁴ National Student Survey (NSS), 2022

⁵ The Complete University Guide, 2023

⁶ Performing at or above the cluster average across
every perspective

⁷ The economic and social impact of the University of
Southampton, London Economics, 2022

THE UNIVERSITY AND ITS REGIONS

SOUTHAMPTON
CLINICAL TRIALS
UNIT (SCTU)

NATIONAL OCEANOGRAPHY
CENTRE SOUTHAMPTON
(NOCS)

UNIVERSITY HOSPITAL
SOUTHAMPTON NHS
FOUNDATION TRUST (UHS)

BOLDREWOOD
INNOVATION
CAMPUS

WINCHESTER
SCHOOL OF ART

AVENUE
CAMPUS

HIGHFIELD
CAMPUS

Find a better quality of life.

Southampton

Southampton is a fantastic place in which to live, work and socialise. Regardless of what life stage you are at, you will find a dynamic and vibrant city that caters for all. With an enviable location on the coast, yet just over an hour from London, the region combines incredible natural beauty with a thriving social scene – making it a desirable place to live! As an ethnically rich city that is growing rapidly, Southampton is benefitting from considerable investments in the region.

The city centre is currently thriving thanks to over £600m of regeneration plans and projects, including the historic Bargate Quarter, with new hotels, homes and transport links. This is a city of growth and transformation, and it is an exciting time to be here.

There is something for everyone in Southampton and the surrounding areas. For outdoor enthusiasts, water sports, sailing and ocean racing are easily available, while the beautiful New Forest National Park is just 30 minutes away. With many excellent local schools and nurseries, families will find a fantastic quality of life, while there's a thriving LGBTQ+ social scene. Multiple faiths are celebrated in the city, and the rich cultural heritage of Winchester is just on our doorstep.

Winchester

On the edge of the South Downs National Park, England's ancient capital, Winchester, is steeped in history and is complemented by a lively atmosphere and a wide variety of pubs and restaurants, museums, theatres and galleries. With direct rail links to London, our Winchester School of Art campus is one of the UK's leading art and design institutions.

The University campuses

The University has five lively and diverse campuses in Southampton, one in Winchester and one in Malaysia.

University Hospital Southampton is the base for the University's Faculty of Medicine. Here, the Southampton Clinical Trials Unit is housed within the purpose-built Centre for Cancer Immunology, which opened in 2018 following a successful £25m fundraising campaign. The hospital campus offers modern laboratories, computer suites, refurbished lecture theatres and a specialist Health Services library.

Three miles east of the hospital campus, our main Highfield Campus is home to state-of-the-art teaching and research facilities, as well as one of the UK's leading music venues, Turner Sims. It also houses our sports complex, the Hartley Library, the Students' Union and Staff Social Centre.

Close to Highfield, Avenue Campus houses most of the humanities disciplines and the Centre for Language Study. It also has a purpose-built archaeology building with state-of-the-art facilities for teaching and research.

A few minutes' walk from Highfield is Boldrewood Innovation Campus. The University's collaboration with Lloyd's Register represents one of the largest business partnerships with any single university in the world. Our £170m campus is the result of this partnership and is home to the Southampton Marine and Maritime Institute.

Situated on the city's waterfront, the National Oceanography Centre Southampton (NOCS) is one of the world's leading research centres for the study of ocean and Earth science.

Close to Winchester city centre, 12 miles north of Southampton, our internationally renowned Winchester School of Art provides studios and

workshops, an extensive specialist library and a well-stocked art supplies shop. The Winchester Gallery is based on campus.

Set just outside Southampton, our Science Park is a hub of innovation, hosting a range of exceptional facilities and home to science and technology businesses from start-ups to multinationals.

University of Southampton Malaysia is home to undergraduate engineering and business programmes in Malaysia. Our brand new campus, opened in 2021, is part of EcoBotanic City in Iskandar Puteri, Johor, offering state-of-the-art laboratories, learning and recreational spaces.

 [View our virtual tours](#)

 [Watch our video](#)



Find out more

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