

Research Newsletter Issue 1

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WWL study recruitment increases by over 1200%

Over the last 10 years Wrightington, Wigan and Leigh NHS Foundation Trust's Research and Development Department has worked hard to promote research opportunities to our patients and raise awareness amongst staff. Thanks to the team's efforts, the Trust has seen an astounding 1204% increase to research studies.

Specialty	2010-2015	2015-2019
Oncology	59	718
Rheumatology	50	276
Paediatrics	22	1136
Diabetic	1	7
ENT	11	46
Orthopaedics	15	397
Medical	18	392
Surgical	0	2
Dermatology	80	17
Gastroenterology	44	605
Reproductive Health	0	88
Anaesthetics	0	338
Total	300	4022



Dr Christos Zipitis, Clinical Director for Research and Development for WWL (during this period) exclaimed: "I always thought we increased recruitment perhaps 3-4 times. **This is more than 13 times higher!** It's very impressive".

Spotlight on Wrightington, Wigan and Leigh NHS Foundation Trust



Research is essential to the development of world leading excellence in clinical care and is central to the promotion, provision, and continuous improvement in the quality and safety of all aspects of the services offered at Wrightington Wigan and Leigh NHS Foundation Trust (WWL). It enables the Trust to continuously develop and improve its services and to attract and retain highly skilled and motivated staff.

Wrightington, Wigan and Leigh NHS Foundation Trust is an acute NHS trust based across four hospital sites in the North West of England. Despite its proximity to Manchester, (which boasts some of the UK's most renowned academic research institutions); this average sized NHS trust has nurtured an impressive research track record over the last decade.

The number of studies it has supported (open to recruitment at the Trust) has steadily grown from just 22 back in 2008/09 to 70 studies during 2016/17 (**218 % increase**). Fifteen of the 70 studies actively recruiting during 2016/17 were commercial contract studies into which 111 patients were enrolled (source: NIHR CRN Clinical Research Network Portfolio 2016/17 annual data report). In parallel with this increase in studies, and with support from the NIHR Clinical Research Network, the Trust has developed its research capacity and capability which have enabled it to attract even more clinical trials and drive further growth.

WWL has a burgeoning interest in biosimilar medicine research and is a great representative example of many smaller NHS organisations across England.

Wrightington, Wigan and Leigh NHS Foundation Trust has recently been involved in the NIHR National campaign for Bio-similar therapies. This campaign has now progressed to the USA and WWL's sheer enthusiasm for biosimilar medicines has been included in the international campaign. Having participated in clinical trials of original biologics in the past, the Trust has embraced the concept of biosimilar medicine trials with equal fervour and dedication.

Christine Birchall, NHS Trust Head of Research, provided a great introduction by telling us what excites her about biosimilar research and why her clinicians are enthusiastic about getting involved.



Christine Birchall, WWL NHS Trust Head of Research

Check out <https://www.nihr.ac.uk/news-and-events/support-our-campaigns/biosimilars/spotlight.htm>

The Research & Development Department (R&D)

The Clinical Director of Research and the Head of Research lead the Research and Development team in supporting, developing and monitoring the growth of research within the Trust and act as a source of information for regulatory queries.

The Research and Development (R&D) Department has enjoyed a long history of working with Researchers in developing high quality research projects, which have led to improved developments in health care and the health and well-being of not only the local community but also the national and international community.

When acting as a host organisation the R&D office facilitate the timely set up of externally sponsored trials and support the Principal Investigators participating in those trials, ensuring all relevant approvals are in place. These include the implementation of Standard Operating Procedures with Support Services such as Pharmacy and Radiology before a research project can take place within our Trust.

Wrightington, Wigan and Leigh NHS Foundation Trust (WWL) clinical trials performance is measured against two national benchmarks to improve the initiation and delivery of all clinical trials approved by the Trust; these are submitted to the National Institute of Health Research (NIHR) on a quarterly basis by the R&D department.

When acting as the sponsor, R&D will be involved in the oversight of the trial by guiding the Chief Investigator and managing any associated risks. Researchers are advised to contact the R&D Office in the early stages of study development so that they can help identify and provide valuable support.

The R&D office ensures the Trust fulfils its legal, regulatory and financial responsibilities relating to research. The department manages risks relating to these responsibilities and this includes an audit of 10% of all active research projects on an annual basis.



The R&D Team

It is mandatory for all research in the NHS to be conducted in line with the Research Governance Framework(s) and the R&D Office is responsible for ensuring that all research meets these requirements.

Research and Development at WWL



The Research and Development Department is currently based at Wrightington Hospital and supports the Trust's Research and Development strategy. There are research bases throughout the Trust: Wrightington has both an administrative base and a clinical area on Ward 5.

At the Royal Albert Edward Infirmary (Wigan) site, the research administrative base is in The Hawthorns together with the Oncology Research Department and a dedicated room for research in the Cardiology Department.

Over the years the Research Department has built up a service which is now attracting international repute for our capability to conduct high quality, ethical and clinically relevant research locally.

Staff within the team have a strong knowledge base of research methodology and Trust procedures. We have an excellent understanding of the needs of the sponsor of the trial, the investigator and the participants.

The Senior Research Nurse Lead is assisted by a team of generic research nurses who support research in all the disease specialities throughout the Trust; this is inclusive of Paediatrics and Midwifery. The Trust also has an active Oncology Research Team who works closely with the Christie Hospital.

The team supports outpatient clinics at the Thomas Linacre Centre, the Hanover Centre at Leigh, the Hewitt Fertility Centre at Wrightington and Leigh Infirmary.

Research is available in most disease specialities. Our mission is to ensure that all WWL patients have access to research.

Our Vision for the future:

- ✓ To attract more commercial activity and increase our research portfolio in even more specialised disease areas, which will give patients access to novel new treatments which are not currently available.
- ✓ To provide face to face Good Clinical Practice training in house sessions to aid professional development.
- ✓ To develop links with Primary Care, so those patients with diseases managed in the community have access to research.
- ✓ To ensure all patients attending the Trust have an opportunity to take part in Research.



Trust Recruitment to Target

Currently Wrightington, Wigan and Leigh NHS Foundation Trust is one of only 3 out of a total of 13 different north west NHS Trusts to be rag rated **GREEN for Trust Recruitment to Target.**

Current research successes

Cardiology hits recruitment figures



It is with great pleasure that we can announce that the Cardiology Research Team has achieved the set the yearly target for recruitment.

The Trust would like to thank our Cardiology Research Team and Cardiologist Specialist Nurses for their amazing energy and hard work to reach this target.

Recent patient feedback on a Cardiology study:

My mum's experience:

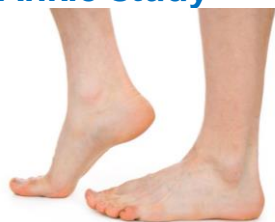
I just wanted to take the time to say thank you for this as Samantha Reddington, Clinical Trials Research Nurse, truly made a worrying time

for my Mum a very positive experience. Many Thanks.

Congratulations to Samantha Reddington, Cardiology Research Nurse, for her dedication, hard work and support.

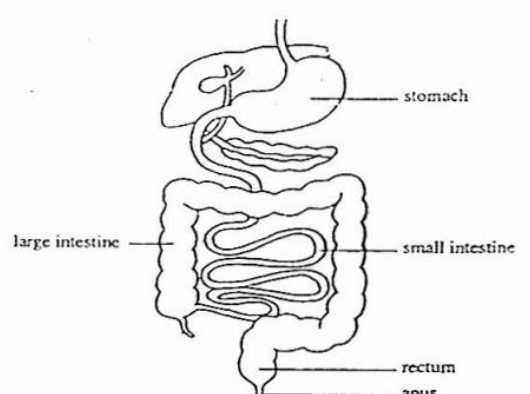
WWL has a study to look at how we can improve accuracy of heart scans for diagnosing heart disease. All patients attending WWL for stress echo cardiograms are invited to take part in this study – to date we have **319 recruits!**

Ankle study



This 10 year post-market observational study is looking at long term survivorship of implants. To date there is currently no long term data for ankle replacement for successful implant longevity. All patients listed for ankle replacements were offered to take part in this study. Wrightington hospital recruited a fifth of the total study recruits – there are 98 participants and Wrightington is the top recruiter in the UK!!!

Gastroenterology study



This study is to assess the impact of Barrett's Oesophagus and its care pathways from a patients' perspective – this is sponsored by WWL. The first stage has been a really successful trial. To date we have 478 recruits and there are plans to do a follow on study.

ENT study



This study was looking at a new drug treatment for the treatment of Nasal polyps. This is a global study WWL is the only site in the UK to recruit a patient*. **This study is no longer recruiting but is in follow up*

WWL status for Greater Manchester on recruitment

I am very proud to note that **WWL sits 5th out of 27 NHS Trusts** for recruitment in the period 2018/9. The table below shows the top 10:

Place	Trust	Actual recruited
1 st	Pennine Acute Hospitals	37122
2 nd	Manchester University Hospitals	20405
3 rd	Salford Royal	6845
4 th	Stockport	3095
5 th	WWL	2144
6 th	The Christie	2120
7 th	East Lancashire	1972
8 th	GM Mental Health	1810
9 th	NHS Salford CCG	1262
10 th	Bolton	1135

Based on patient population this is a massive achievement!

Christine Birchall
Head of R&D, Innovation & Clinical Trials
Strategy & Planning

Well done the WWL Research team!

Meningitis study achieves over 1000 recruits

Meningitis Study: Evaluating the effect of immunisation with group B meningococcal vaccines on meningococcal carriage.



Working with the University of Oxford, and going into sixth form colleges, Chief Executive Andrew Foster congratulated the members of the Clinical Trials Unit Research Team for recruiting over a 1000 patients to a study trial on meningococcal vaccines.

This study evaluates the carriage of pathogenic N. meningitis species in adolescent populations being immunised with either 4CMenB or MenB-fHBP, when compared with those receiving no vaccine.

WWL Research and Clinical Trials Staff



BACK ROW: Research Nurses and Clinical Trials Assistants Claire Williams, Valerie Parkinson, Nicola Pemberton (Paediatrics), Tracey Taylor (Senior Research Nurse), Caroline Dandy, Christopher Moore, Katja Van De Snepscheut-Jones and David Wilcock.

FRONT ROW: Clinical Trials Assistants Linzi Heaton, Shannon Briggs and Josh Cooper.

Greater Manchester Clinical Research Awards Winners - Outstanding Contribution

NIHR | National Institute
for Health Research



The winners of the 2018 Greater Manchester Clinical Research Awards were revealed during an evening of celebration on Thursday 22 November. Staff from the region's hospital Trusts, primary care centres and other partners gathered in Manchester city centre for the sixth-annual ceremony to toast excellence in health research delivery.

The event was organised by NIHR Clinical Research Network, Greater Manchester (CRN GM) in association with industry partner Sanofi, who kindly sponsored the Research Team of the Year award. During the 2018 ceremony, individuals and teams were recognised for their efforts in 11 categories.

In 2017, WWL's Oncology Research team, in collaboration with The Christie Hospital, pioneered the delivery of a commercial trial to lead the way for further pharmaceutical companies to explore this way of working. WWL and The Christie Hospital have worked hard in setting up the trial that has been operated simultaneously across both sites.

The trial provides patients with more options to access research and different treatments closer to home. It was the first of its kind in the region and paved the way for the National Institute of Health Research (NIHR) to increase opportunities for patients to participate in, and benefit from research, in line with the government initiative 'Care Closer to Home.'

GM CRA Winners for Outstanding Contribution

Oncology Collaboration – The Christie Breast Cancer Research Team & WWL Oncology Research Team
(The Christie NHS Foundation Trust & Wrightington, Wigan and Leigh NHS Foundation Trust)

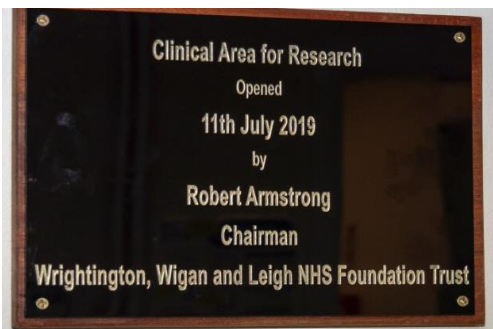


Angela Power, Senior Oncology Research Nurse at WWL said: "The team is overjoyed to have been announced the winner of the 'Outstanding Contribution' award, as it has proven to be an excellent innovation and service development for the patients of the Wigan Borough. This brings oncology research closer to the patients and we look forward to more partnership working in the future.'

WWL was successfully shortlisted in three award categories, against very strong competition. Tracey Taylor, Senior Research Nurse was named runner up in the 'Research Nurse of the Year' category and the Divisional Clinical Research Champions were shortlisted for 'Research Team of the Year'.

The Chairman, Robert Armstrong attended the Ward 5 dedication ceremony at Wrightington Hospital today 11th July 2019:

“Welcome to the opening of our dedicated Research Area. Research has always been undertaken at Wrightington, Wigan and Leigh hospitals. Indeed, we are in the place where one of the most significant and life changing procedures was researched, piloted and developed – the artificial hip.



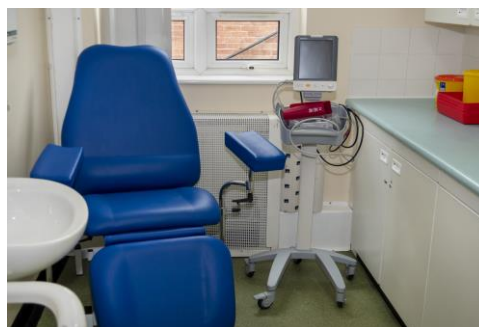
WWL has, quite rightly, renewed its focus on research activity and the benefits to patients, staff and advancing clinical care. A recent National Institute for Health Research (NIHR) report highlighted that WWL in 2018/19 recruited 2420 patients, for our sector this was one of the best increases and it put us slightly ahead of The Christie. As a comparison, 10 years ago we only had 19 patients in NIHR studies.

Why is research so important? Studies by the NIHR and a peer reviewed journal GUT (British Society of Gastroenterology) shows a direct association between high level research activity and lower levels of patient mortality following emergency admissions. Also, Trusts that are research active have better outcomes than those who undertake lower levels of research.

Up to this point, clinical research has had not assigned accommodation to see patients. Patients were seen in areas borrowed from Out Patients' or even on corridors – this was not acceptable for a patient centred service where, by its very nature, patients will feel anxious about what is to happen to them as part of their treatments.



The Three Wishes charity (our own WWL charity) has funded the phlebotomy chair and blood pressure monitor and I am pleased to see the use to which charitable funds are making a difference to our patients.



There are so many people who have made this possible: Christine Birchall, our Head of Research and Clinical Trials; Tracey Taylor who is our Lead research Nurse and has spent a great deal of her time in getting the accommodation fit for purpose; the Estates department who have supported the refurbishment, and to everyone who has contributed to bringing this facility to life - a big word of thanks.

I hope this Unit will enhance the care we give to patients and help to improve, through Research and Clinical trials, the outcomes for many, many people. I would like to dedicate the Unit officially open.”

Robert Armstrong, Chairman, WWL



Robert Armstrong, WWL Chairman, and Christine Birchall, Head of Research and Clinical Trials

Interested in doing Research?

Introduction to Good Clinical Practice (GCP)

What is GCP training?

Clinical Practice (GCP) is the international ethical, scientific and practical standard to which all clinical research is conducted. Compliance with GCP provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable.

Why do you need GCP training?

Everyone involved in the conduct of clinical research must be competent to perform their tasks, qualified by education, training and experience. This is a requirement of the [UK Policy Framework for Health and Social Care Research](#), the policy covering all research in the NHS in England, and in law (SI 2004/1031, Schedule 1, Part 2, 8) for those people working on clinical trials.

How often do you need to complete GCP training?

This is decided by your Trust/employer, as the answer depends on the research you are involved in, and your previous experience. For clinical trials, the Medicines for Human Use (Clinical Trials) (2004) regulations require that all staff are trained to carry out their duties on each study they are working on. This is not time bound. If you have just had participated in training and a regulatory change is made, you will need to be informed of these changes and understand their implications for your practice.

I'd like to contact to someone about GCP

If you would like to access the GCP e-learning courses or book on to a face to face workshop, please log in to [NIHR Learn](#).

If you would like information about NIHR Learn and details about how to access it, please visit the [NIHR Learn help site](#).

If you have any other queries about learning programmes, including GCP, please complete the [NIHR Learn help form](#) and we will get back to you.

Upcoming Events

Event 1

18/10/2019

GCP Introduction training

Time: 09:00 to 13:00

<https://www.medicsevents.co.uk/events/greater-manchester-gcp-refresher-royal-albert-edward-infirmary-wigan/>

Medical Education Centre - RAEI

Event 2

06/12/2019

GCP Introduction training

Time: 09:00 to 16:30

<https://www.medicsevents.co.uk/events/greater-manchester-gcp-introduction-royal-albert-edward-infirmary-wigan/>

Medical Education Centre - RAEI

The R&D Committee is grateful to RUTH KILLEN for producing this newsletter