

Medicine Research Newsletter

Inside This Issue

- 1 Introducing new Clinical Director
- 2 Outgoing Clinical Director
- 3 Research & Clinical Trials
- 4 Partnerships – Clinical Research Network
- 5 Partnerships – Radiology
- 6 Partnerships – Pharmaceutical Partnerships
- 7 Gastroenterology
- 8 Cardiology
- 9 Respiratory
- 10 Diabetes
- 11 Stroke
- 12 Emergency Medicine
- 13 Recruiting to Trials
- 14 Interested in doing Research//Upcoming Events

New Clinical Director

Introducing Ian Trail as the new Clinical Director who will join Christine Birchall and her team in leading the research agenda

The Research team welcome Professor Ian Trail, Consultant Orthopaedic Surgeon as the new Clinical Director for Research & Development, and look forward to working with him in further developing research which influences quality outcomes for our patients. Ian took up the appointment from April 1st.



Professor Ian Trail M.D., F.R.C.S.Ed., F.R.C.S.E.
Clinical Director for Research, Surgery
Consultant in Hand and Upper Limb Surgery



Dr V J Karthikeyan MD FRCP (London) FESC,
Consultant, Interventional Cardiologist & Research Lead, Division of Medicine

Outgoing Clinical Director

Dr Christos Zipitis served as the CD for 5 years. During this period he raised the profile of research in the Trust which helped WWL gain a lot of recognition and awards. We would like to thank Christos for his hard work and dedication to the Research Department.



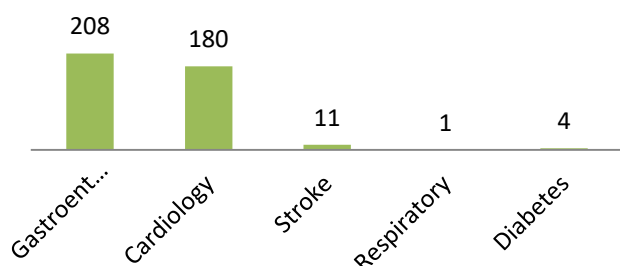
Dr Christos Zipitis MBChB(Hons), MPH, FRCPCH
Consultant Paediatrician and Neonatal Lead

Please see below an overview of WWL study recruitment between 2010-2015 and 2015-2019:

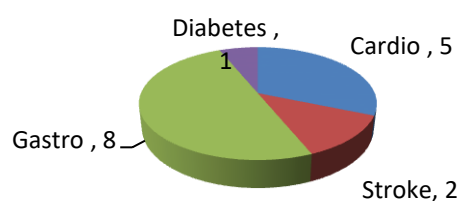
Specialty	2010-2015	2015-2019
Oncology	59	718
Rheumatology	50	276
Paediatrics	22	1136
Diabetic	1	7
ENT	11	46
Orthopaedics	15	397
Medical	18	392
Surgical	0	2
Dermatology	80	17
Gastroenterology	44	605
Reproductive Health	0	88
Anaesthetics	0	338
Total	300	4022

As Dr Christos Zipitis, (Clinical Director for Research and Development for WWL in this period) commented: "I always thought we increased recruitment perhaps 3-4 times. **This is more than 13 times higher!** Very impressive."

Medicine recruitment to date March 2019



Number of Studies in Medicine Division - March 2019



RESEARCH AND CLINICAL TRIALS

Over the years, Research has built up a service which is now attracting international repute for its capability in conducting high quality, ethical and clinically relevant research within our community

INTRODUCTION

Welcome to the Clinical Trial's Unit. The Clinical Trials' Unit is based at Wrightington Hospital and supports the Research & Development strategy at Wrightington, Wigan and Leigh NHS Foundation Trust.

Research is a core activity of the Trust and is central to the promotion, provision and continuous improvement in the quality and safety of all aspects of the service we offer.

All research trials conducted at Wrightington, Wigan and Leigh NHS Foundation Trust are completed to international standards by an experienced and qualified staff who are also familiar with robust record information systems.

**AWARD WINNING TEAM
PHOTO**



WHY DO CLINICAL TRIALS?

Assess the safety and effectiveness of a new medication or device on a patient with a specific illness (e.g. patients who have been diagnosed with Rheumatoid Arthritis).

Assess whether the new medication or device is more effective for the patient's condition than the standard therapy.

Assess the safety and effectiveness of a different dose of a medication than is commonly used (e.g. 10 mg dose instead of 5 mg dose).

Assess the safety and effectiveness of a medication or device which is already on the market for a new indication (i.e. a disease for which the drug is not specifically approved)

BENEFITS OF RESEARCH

Research provides a trial management service which includes supporting clinicians in carrying out high quality, ethical and clinically relevant research in our local community.

Staff within the department have a strong knowledge base of research methodology and Trust procedures. They have an understanding of the needs of the Sponsors of the trial, Investigator and the Participants.

By taking part in research, participants and their Consultants will be at the forefront of evolving new treatments in their disease area.

The department also provides for the following:

- Ensures respect for the dignity, rights, safety and wellbeing of study participants
- **Facilitates patient liaison and recruitment**
- Employee dedicated, experienced and qualified research nurses
- **Maintain and monitor quality control by adhering to Standard Operating Procedures (SOPs)**
- Ensure that governance issues are appropriately managed
- **Ensures that study documentation is correctly managed during a trial and appropriately archived**
- Provides the necessary assurance that all clinical trials are carried out in a safe and ethical way
- **Ensures that support services such as Radiology and Pharmacy are consulted appropriately during the planning of the clinical trial**
- Provides a definitive point of contact for all issues pertaining to clinical trials
- **Access to a large range of trials which covers a comprehensive range of hospital specialities**



AREAS OF RESEARCH

Specialist Services

- Orthopaedics
- Dermatology
- Oncology
- Rheumatology
 - Rheumatoid Arthritis
 - Lupus
 - Psoriatic Arthritis
 - Ankylosing Spondylitis

Medicine

- Gastroenterology
- Diabetes
- Stroke
- Respiratory
- Cardiology

Surgery

- Obstetric/Gynaecology
- Fertility
- Paediatrics
- ENT
- Ophthalmology
- Anaesthetic & Theatres

Infection Control



Contact Details

Research Administration 01257 48 8229

researchadmin@wwl.nhs.uk

PARTNERSHIPS



1. Clinical Research Network (CRN)



The NIHR Clinical Research Network Coordinating Centre manages the [Clinical Research Network \(CRN\)](#) on behalf of the Department of Health and Social Care. The CRN makes it possible for patients and health professionals across England to participate in clinical research studies, in both the NHS and in the wider health and social care environment.

The CRN provides the infrastructure that allows high-quality clinical research and meets the costs of using NHS staff that support research and provides specialist training so that patients can be confident that research is being delivered by trained, experienced NHS staff.

The CRN also meet the costs of using NHS facilities, such as scanners and x-rays that are needed in the course of a study, so that research is not subsidised with NHS funding that has been provided for patient care.

At the heart of CRN activities is the [NIHR CRN Portfolio of studies](#). This consists of high-quality clinical research studies that are eligible for consideration for support from the CRN in England. We also provide the [Study Support Service](#) that helps researchers and the life sciences industry plan, set up and deliver high quality research to time and target in the both the NHS and in the wider health and social care environment, across England. We provide this service for all studies eligible for our support, regardless of location, study type, study size, therapy or research area. Whether your study is medical, diagnostic, pharmaceutical, bio-tech or is looking at healthy populations or people with social care needs, we can help.



2. Radiology

The Radiology/X-Ray Services at Wrightington, Wigan and Leigh NHS Foundation Trust are modern and well-equipped services with some of the latest, most technologically advanced equipment. We offer a comprehensive range of diagnostic procedures in our hospitals to support our clinical teams in the diagnosis and appropriate management of patients with a wide variety of conditions. Our technologies include PACS, a system that makes x-rays (images) instantly available to doctors at many computers throughout our hospitals. Radiology/X-Ray images are now sent electronically direct to the GP surgery.

Given the role of Radiology in so many different patient journeys it would seem logical for there to be a role for it to play in any research looking at the diagnosis, treatment or management of these patients and their disease. This is true at least in that we have, and are, involved in a wide range of research Trials looking into a variety of diseases or conditions and their treatment.

So what do we actually do for research trials?

Diagnostic imaging investigations are utilised in a number of ways by research studies. It may be that for a patient to be eligible for a trial that they must have a confirmed diagnosis. In this circumstance a scan, X-Ray or other investigation may be performed at the screening stage to confirm the patient is eligible to be enrolled onto the study.

In the same manner it is also quite common for imaging to be performed at the screening phase to rule out the patient having certain exclusion criteria. In a similar way, occasionally radiological examinations may be used towards the end of a study to ensure that a known side effect of a study treatment hasn't caused an untoward effect.

Imaging is also used during a wide range of surgical procedures to give the surgeon detailed and real time information and guidance during the procedure. As such radiology can often be involved in research studies that are looking at new surgical procedures or devices.

Aside from just producing images; the Radiology Department are also involved in providing a range of therapies and interventional procedures, and are often involved in studies looking directly at these. An example of this would be a trial comparing various treatments to some of the procedures we perform in Interventional Radiology.

Probably the most common use for Imaging in research is as a consistent, unbiased, and reproducible tool, to track and evaluate the response in a patient's body to a particular drug or treatment. A prime example of this would be a cancer trial where we would perform a baseline scan at the start of a trial and take measurements of the patient's tumour/s. Then at periodic intervals, or perhaps just the end of the treatment period we shall repeat the scan and measure and compare the patient's response to the treatment.



Lee Unsworth is the Radiology lead for research

3. Pharmaceutical Partnerships

"Almost every member of the public takes some kind of prescription drug and medication, and if providers approach the manufacturers of those drugs with a collaborative mind set, innovative solutions can create significant benefits for both parties and, most importantly, the consumer."

Michael J Dowling, President & CEO, Northwell Health

Why does the NHS work with pharmaceutical companies doing research?

The NHS and the Association of the British Pharmaceutical Industry (ABPI) have celebrated their respective 70th anniversaries. The histories of these two organisations have been inextricably linked since 1948 and the relationship continues to go from strength to strength.

The NHS is a source of great pride for the vast majority of us. The health service is driven by the doctors and nurses and the other frontline staff who deliver the high-quality care, and we have all relied on them at some point of our lives to help us and our families get better. But the NHS is not exclusively responsible for our health.

Scientists and clinicians in pharmaceutical companies work closely with doctors, pharmacists and nurses in the NHS to bring medicines to patients. Today, over 80% of the medicines used by the NHS have been researched and developed by pharmaceutical companies that are members of the ABPI. In 2016 alone, the industry invested over £4.1 billion just in the UK on R&D, looking for breakthroughs for conditions like cancer, dementia and rare genetic diseases. There are 7,000 potential new medicines in the pipeline right now that may someday benefit the NHS.

Dr Sheuli Porkess, Deputy Chief Scientific Officer at the ABPI

In short:

- It allows health professionals to push the boundaries of clinical management
- It offers patients an opportunity to have access to new drugs.
- It offers opportunity to accumulate evidence that would help to improve and develop new clinical treatments

Pharmacy



Pharmacy at RAEI



Pam Bootle, Research link

The department provides a wide and diverse range of services to inpatient s and outpatients, clinicians, nurses and other health care professionals across the whole Trust. Traditional services such as dispensing medicines, ward and clinical services and provision of medicines information are complimented by newer services such as discharge planning and reducing medication errors. The Pharmacy departments across the Trust can provide information to patients on medicines dispensed by Trust doctors and this service can be accessed by telephoning the departments.

Gastroenterology

Gastro Clinical Trials currently being run at Wrightington, Wigan and Leigh NHS Foundation Trust:

- Attire
- Pred-4
- UK Primary Biliary Cholangitis (PBC)
- UK –AIH
- Primary Sclerosing Cholangitis (PSC)
- BOBO
- SPIT
- IBD BioResource

The target set for WWL NHS Foundation Trust for the Greater Manchester Network for 2018/2019 was 165
- we achieved **208**.

BOBO

The aim of this study is to explore ways of improving follow up care for patients with a diagnosis of Barret's Oesophagus. The research will inform on the development of a follow up intervention aimed at improving the patient journey.

SPIT

First wave directed towards colorectal oesophageal cancer. Aims to create an accurate predictive test which 1) Identifies individuals with low risk of developing specific diseases so that they can be saved from undergoing expensive, invasive, and unpleasant tests and 2) Identifies patients at high risk of developing disease so that they can be treated by minimally invasive techniques and avoid getting the disease at all.

Pred 4

This study aims to identify clinically useful generic and non-generic factors that predict serious Adverse Reactions so that these drugs can either be avoided or patients will receive more intensive monitoring.

PANTS

Anti-TNF drugs Infliximab and Adalimumab have greatly advanced the treatment of Crohn's Disease. However, some patients do not respond to treatment, others lose response to the drugs with time, and some patients occasionally experience unpredictable side effect which may be severe. This study aims to identify why some patients develop these problems whilst others do not. It is hoped to develop a test to predict which patients are likely to benefit or at least suffer less side effects.

The information gathered will allow these drugs to be used in a safer, more cost effective way, tailored to the individual patient.

IBD Bio Resource: Crohn's Disease and Ulcerative Crohn's.

A study looking at how genes and environmental factors influence disease and response to therapy. Aim is to gain insight regarding the course of disease, potential new therapies and treatment approaches for IBD to reduce the burden of disease and find a cure.

Hep E

The study determines whether a Hep E injection is a cause of acute deterioration in patients with the liver disease in the UK.

Cardiology

Research within Cardiology at Wrightington, Wigan and Leigh NHS Foundation Trust offers patients wishing to take part, a wide range of studies ranging from Invasive trials, to trials that aim to enhance patient knowledge regarding the medication's they take to treat Heart Failure.

We currently have three research active Cardiology consultants, Dr Ayyaz Sultan, Dr Haytham Hamden and Dr VJ Karthikeyan, with other consultants completing GCP training to allow them to also get involved with research. The three senior consultants currently involved work across the various Trust sites. Dr Sultan is the Research Lead for the National Institute of Health Research (NIHR) for the North West and Greater Manchester, and is a driving force in bringing in new research into the Trust.

Cardiology research at WWL is thriving. From April 2018-2019, our dedicated research team recruited 201 patients into various Cardiology trials. This surpassed the target that was set by the NIHR. A trial run by Dr Hamden and our Cardiology Research Nurse, Samantha Reddington, called EVAREST, has enrolled over 300 patients into the trial since opening in November 2018. Our Trust is currently the highest recruiting Trust in the Country for the EVAREST trial.

Cardiology Clinical Trials currently being run at Wrightington, Wigan and Leigh NHS foundation Trust:

- Evarest
- ISCOMAT
- AFIII Registry
- BHF Senior Rita Trial

If you would like any information on any of the above trials or information about the research in Cardiology at Wrightington, Wigan and Leigh NHS Foundation Trust, please get in touch using the following details:



Samantha Reddington
Cardiology Clinical Research Nurse
01942 822014
Samantha.Reddington@wwl.nhs.uk

or

Research
01257 488264
Researchadmin@wwl.nhs.uk

Respiratory

Dr Abdul Ashish has been appointed the NIHR Clinical Research Network Greater Manchester (CRN GM) specialty lead for Respiratory Disorders. This is a great achievement.



He is a Consultant Respiratory Physician with Wrightington, Wigan and Leigh NHS Foundation Trust (WWL), based at the Royal Albert Edward Infirmary in Wigan and is also WWL's lead clinician for respiratory medicine and clinical director for scheduled care.

Dr Ashish, who has special interests in Interstitial Lung Disease (ILD) and Bronchiectasis, has long been passionate about clinical research. Before he joined WWL in 2011, he spent two years as a research fellow at Liverpool Heart and Chest Hospital. In 2015 he earned an MD from the University of Liverpool for his work on "Transmissible Pseudomonas strains" in adult Cystic Fibrosis patients.

Dr Ashish said: "It is my belief that access to clinical research should be equitable and accessible to all sites for all patients across Greater Manchester. I want to support our academic centres by recruiting patients from across GM into clinical trials led by them and promote research across the District General Hospitals. I am really looking forward to working towards this goal across GM.

I see Greater Manchester as a rich resource for respiratory research. We are already recruiting well with the populations around the Salford and Wythenshawe areas, but we have an excellent opportunity to reach out more widely into the other boroughs.

My areas of specialisation are Interstitial lung disease (conditions leading to scarring in the lung) and bronchiectasis (condition leading to recurrent lung infections).

I work with a wonderful set of colleagues and specialist nurses, dedicated to providing clinical care of the highest standard. I am also passionate about improving the care and access to new therapies for our patients, by collaborating with colleagues and engaging in clinical research.

Recently, I have taken up the post of Respiratory Speciality Lead for research across Greater Manchester. This position will help me collaborate with scientists and academic colleagues working across GM and the rest of the UK to bring research into WWL and other Trusts across GM, ultimately helping us improve respiratory care across our region."

Respiratory Clinical Trials being run at Wrightington, Wigan and Leigh NHS foundation Trust:

- ELLIPTA RESP
- INSMED 212
- INS-MED 312

Diabetes



Diabetes research can't happen without the help of people living with diabetes.

You can play a vital role by taking part in a research study or trial. Scientists need your help to prevent diabetes, find new treatments, improve care, and ultimately, stop diabetes in its tracks. But before new treatments can benefit people living with diabetes, they must be carefully tested to work out if they're safe, what the side effects are and whether they're better than treatments we already have. By volunteering to take part, you could play a crucial part in the fight for a world where diabetes can do no harm.

You can get involved in research at any time, but did you know many clinical trials testing new treatments to stop Type 1 diabetes in its tracks can only recruit people within the first six months of their diagnosis?

We have recently participated in the following Diabetic Clinical Trials at Wrightington, Wigan and Leigh NHS foundation Trust:

- **[ADDRESS-2](#)** (After Diabetes Diagnosis REsearch Support System-2) whose purpose is to find children and adults aged 16-60 years who are newly diagnosed with type 1 diabetes and their brothers and sisters who might be interested in taking part in future diabetes research studies. This study is meeting the challenge and recruiting people with Type 1 diabetes to clinical trials pioneering new immunotherapies to slow or stop Type 1 in its tracks.
- **[TrialNet](#)** is an international network of leading academic institutions, scientists and healthcare teams dedicated to the prevention of Type 1 diabetes, by working with people living with Type 1 diabetes and their families.
- **[StartRIGHT](#)** – a pilot study getting the right classification and treatment from diagnosis of Diabetes. This study aims to achieve more accurate early classification of diabetes and identification of which patients will rapidly require insulin treatment.

If you would like any information on any of the above trials or information about the research in Diabetes at Wrightington, Wigan and Leigh NHS Foundation Trust, please get in touch on the following details:

Research
01257 488264
Researchadmin@wvl.nhs.uk



Phil Paterson, Research Nurse

Stroke

Acute Stroke Services

The Stroke Unit is led by Dr Sunil Herath and Dr Appu Suman who are both Consultants in General Internal Medicine and Geriatric Medicine. They are supported by a multidisciplinary team who are experts in the field of stroke medicine. The Stroke Team are dedicated to providing the best care and outcomes they can for stroke patients. The Team is able to offer rapid and early diagnosis following a suspected stroke using the most advanced techniques and technology including CT and MIR Scanners. This means that patients receive the right treatment as quickly as possible which can help speed up recovery.

We currently have the following Stroke Clinical Trials being run at Wrightington, Wigan and Leigh NHS foundation Trust:

- **AFGEN UK** (Atrial Fibrillation General Long-Term Registry) extension is a multi-centre study being conducted in the UK, enrolling at up to 1650 patients with atrial fibrillation. The purpose of the registry is to record how patients with atrial fibrillation are managed and it will also be used to develop practical recommendations to improve the treatment of atrial fibrillation at local, national and international levels.
- **SPATIAL – a feasibility Study of Prisms And Therapy In Attention Loss after stroke**
Sponsored by the University of Manchester, Unilateral Spatial Neglect (USN), also known as spatial inattention, is a syndrome that can occur after stroke which results in impaired attention to one side (most often the left). Spatial inattention often makes it difficult for patients to fully engage in therapy and may impede recovery. Prism Adaptation Training (PAT) is a possible therapy for inattention. The study will determine the feasibility (including acceptability) both of delivering the intervention within the clinical setting and of conducting a trial, and will add to existing evidence on the proof of concept for the value of the intervention in the clinical setting. We will recruit and randomise patients with spatial inattention to one of two trial arms: an intervention group (occupational therapy including PAT) and a control group (occupational therapy alone), in a 3:1 ratio and stratified by site.
- **TriMethS** – A novel urinary biomarker for minor stroke and transient ischaemic attack. TriMethS is a potential biomarker to facilitate diagnosis in cases of suspected Transient ischaemic attack (TIA) or minor stroke and large scale study is needed because we have validated its presence and higher levels in stroke/TIA patients in an independent prospective study.

If you would like any information on any of the above trials or information about the research in Stroke at Wrightington, Wigan and Leigh NHS Foundation Trust, please get in touch on the following details:



Claire Hill
Stroke Clinical Research Nurse
 01942 822014
claire.m.hill@wvl.nhs.uk

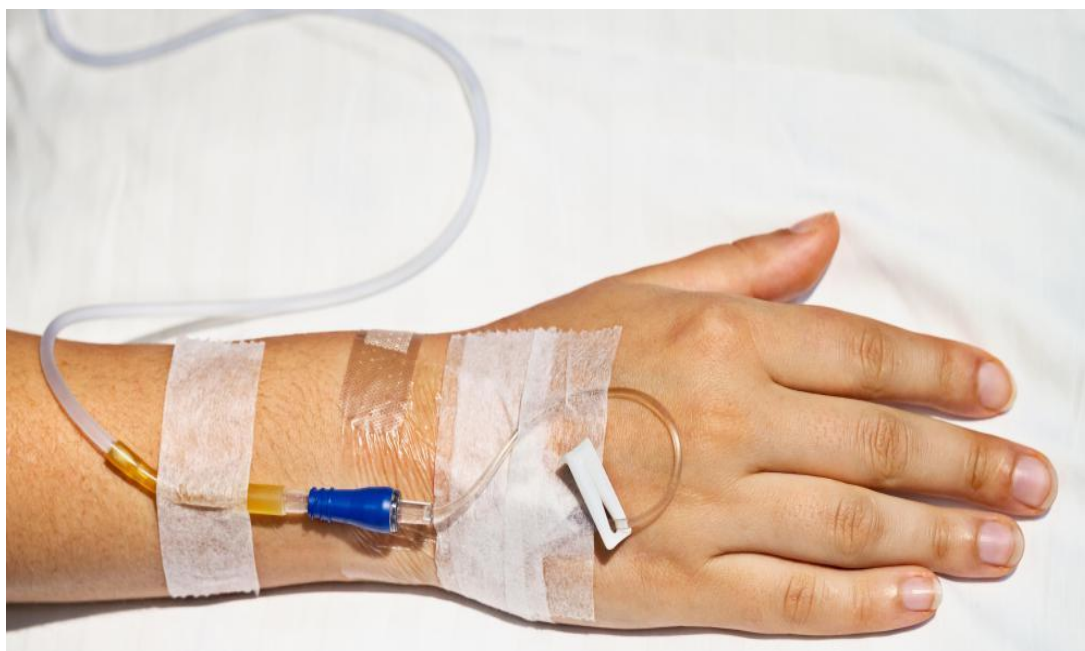
Emergency medicine

The Emergency Care Centre formally known as the Accident & Emergency opened in September 2004 as part of the Phase Four upgrade at the Royal Albert Edward Infirmary in Wigan.

There is a dedicated team of Advanced Practitioners who work as clinicians, qualified to master's degree with prescribing qualifications. They independently assess, diagnose, manage and refer patients within the Emergency Care department.

Intravenous drug compatibility assessment: an evaluation of hospital practices study

The purpose of this study from Reading University is requesting access to commence research involving Intensive care Unit (ICU) nurses to evaluate the practice surrounding the administration of multiple drugs intravenously down the same line, and to obtain information about the drug combinations that you would like to have compatibility information on, for the purpose of testing them experimentally.



If you would like any information on the above trial or information about the research in Emergency Care at Wrightington, Wigan and Leigh NHS Foundation Trust, please get in touch on the following details:

Research
01257 488264

Researchadmin@wwl.nhs.uk

or

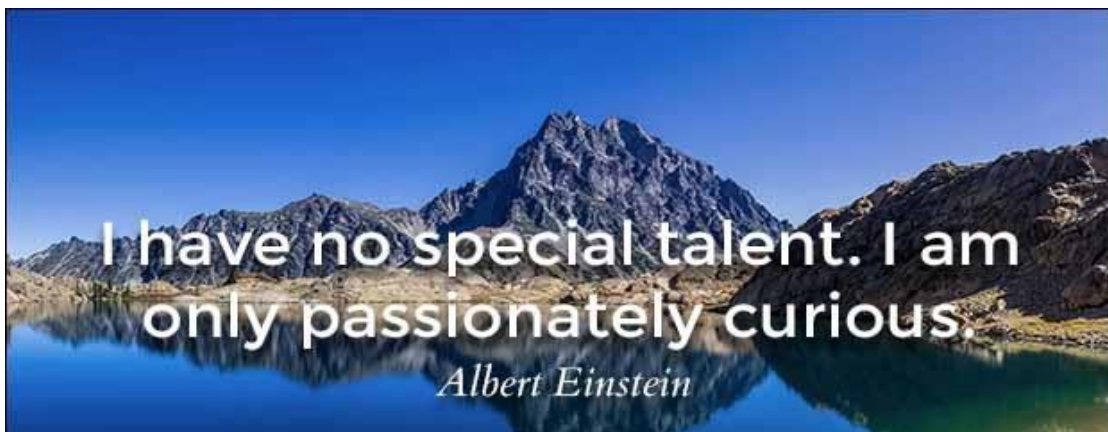
Sheena Wright
Acting Matron, Critical Care
01942 82 2380

Sheena.L.Wright@wwl.nhs.uk

RECRUITING TO CLINICAL TRIALS:

TOP TIPS for RECRUITMENT

- See it as part of daily life
- Understand the relevance for career development
- Participate in the whole process
- Use multiple resources
- Make it personal
- Make it achievable
- Go with your interest
- Only measure stuff you can use
- Don't think you need a sample of thousands
- Use appropriate methodology
- Give people the option



Interested in doing Research?

Introduction to Good Clinical Practice (GCP)

What is GCP training?

Good 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.

Upcoming Events

Event 1

14/11/2019

Research Catalyst Event

Registration 8.30 – 9.15am

Time: 09:15 to 16:00

Discussing access to funding for research, the Research Design Service and 'Open Space' to explore and support our staff to develop research questions

Wrightington Conference Centre

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