Student handbook for placements in research

Authors:
Angela Grange, Claire Coulson, Emma Giddings, Kelly Young, Paula Sharratt, Lynn Johnston & John Hiley

Version 1: April 2012
Dear Student Nurse,

We would like to take this opportunity to introduce ourselves to you as Research Nurses / Clinical Studies Officers working in Bradford and Airedale.

The Research Practice Network, whose members represent NHS organisations in Bradford, Airedale and the West Yorkshire Comprehensive Local Research Network have been working with colleagues at the University of Bradford to offer you the opportunity to spend some time working alongside Research Nurses / Clinical Studies Officers as part of your clinical placement.

As a student healthcare professional the importance of evidence based practice is emphasised from the outset of your course. Research and evidence based practice will be a constant theme throughout your career as a health care practitioner, as it is integral to the delivery of high quality patient care.

Research Nurses / Clinical Studies Officers play a key role in ensuring that patients are given the opportunity to participate in well-designed research studies as part of their care in the NHS. The findings of this research will inform and improve future practice for patients.

The role of the Research Nurse / Clinical Studies Officer is diverse and interesting, and no two days are the same. There are many facets to the role from the recruitment of patients to exciting research studies offering new treatments and technologies, to presenting results from your own research at national and international conferences. Spending some time with a Research Nurse / Clinical Studies Officer whilst on your placement will give you a taste of the world of research in the NHS and potential career opportunities.

If you would like to arrange to spend some time with a Research Nurse / Clinical Studies Officer during your placement please contact the person above.

Best wishes,

Angela Grange
Lead Nurse Clinical Quality & Research/Trust Lead, Innovation (on behalf of the Research Practice Network)
Bradford Teaching Hospitals NHS Foundation Trust

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**Objectives for your Research Placement**

For you to:

1. Be able to demonstrate an ability and confidence to question nursing practice in your clinical area
2. Develop an understanding of the research process
3. Develop an awareness of the role of the Research Nurse in the NHS
4. Develop an awareness of resources available to support research in the NHS
5. Develop a research question to address any gaps in evidence in your area of practice (Year 3)
Why engage in research

Studies suggest that patients who receive care in research-active institutions have better health outcomes than patients who are treated in a non-research environment, so by joining the research community you are actively helping to drive up the standard of healthcare for your patients. By investigating the cause and course of diseases and how best to treat them, you are also helping to establish ‘what works’ and build the body of evidence that can lead to a positive change in future care.

The importance of Research within the NHS

The Department of Health’s strategy to improve the health of the nation continues to place research at the forefront of the NHS. The recent White Paper *Equity and excellence: liberating the NHS* (DH 2010) highlights research in terms of quality, transparency and value for money, with the aim of achieving health outcomes as good as anywhere else in the world. It aims to deliver quality care from evidence based practice which is thoroughly researched. The NHS has a constant challenge to provide a service that is up to date and efficient. Health research plays a key role in this service by using the evidence from studies to support health strategies and changes in medical practice.

The NHS now has a thriving research culture that promotes fairness of access across England for patients and health professionals to take part in multi-centre studies. As a member of a clinical research team you will play a key role in contributing to this research culture through clinical trials and/or health related research, therefore continually improving the quality and choices available for patients and healthcare as a whole.


Liberating the NHS, Equity and Excellence:  
National Institute for Health Research

The National Institute for Health Research (NIHR) is the “research arm” of the NHS. The role of the NIHR is to improve the health and wealth of the nation through research.

NIHR Clinical Research Networks

- Provides the infrastructure that allows high-quality clinical research to take place in the NHS
- Help set up clinical studies quickly and effectively
- Supporting life sciences industry
- Fund research support posts in the NHS and provide training to research workers
- Run PPI initiatives to ensure patients’ needs at the centre of research activity
- Run CSP - a system through which researchers can apply for permission to run a clinical study in the NHS
- Provide funding to meet the costs of using facilities such as scanners and x-rays that are needed in the course of the study
- Provide practical help in identifying and recruiting patients onto Portfolio studies on time and on target

NIHR CRN Portfolio

- Consists of high-quality clinical research studies
- Activity data from the NIHR CRN Portfolio is used to inform the allocation of NHS infrastructure for research
- Supports the performance management of the Clinical Research Network
The six topic networks of Cancer, Stroke, Diabetes, Dementia and Neurodegenerative, Mental Health and Medicines for Children are complemented by the Primary Care and Comprehensive Clinical Research Networks.

West Yorkshire Comprehensive Local Research Network

The West Yorkshire CLRN operates as part of the NIHR Comprehensive Clinical Research Network in England. It is part of the NIHR and forms part of the UK Clinical Research Network. The Networks support and deliver high quality clinical research studies.

The WYCLRN streamline the research management function for NIHR portfolio studies supported by the networks and provides the NHS infrastructure to support clinical research across all areas of disease and clinical need by:

- Managing Specialty Groups to give focused clinical expertise,
- Having access to the national portfolio of studies,
- Funding NHS Service Support Costs for portfolio studies.
With a budget of approximately £12m per annum, the WYCLRN provides funding in the following ways:

- **Service support costs**
  - Clinical infrastructure (consenting patients/retrieving outcome data)
    - Clinical sessions
    - Research nurses

- **Key service support**
  - Pharmacy, Radiology, Pathology
  - Translators, clinical trials co-ordinators, information managers

- **Research Capability Funding (RCF)**
  - Staff costs of researchers between portfolio grants
  - Staff costs of researchers who are awaiting portfolio funding.

**The Role of the WYCLRN Lead Nurse**

“To support, lead and co-ordinate all research nurses/staff allied to WYCLRN across the region to develop a workforce that produces the highest levels of quality and patient safety in clinical research and helps to meet the CLRN objectives”

**The Role of a Clinical Research Nurse**

A Clinical Research Nurse participates in the recruitment of patients to clinical trials or academic research projects. When working on clinical trials the Research Nurse monitors the patients and observes for side effects during the course of the trial. An important aspect of the role is the maintenance of accurate and comprehensive records of data derived from the research studies. As studies will range from simple observational ones to complex interventional studies using investigational medicinal products, the Clinical Research Nurse needs to be innovative and flexible to meet the challenges of this role. Providing a high level of patient care and maintaining patient safety is essential as well as being an advocate for the patient enrolled in the study. The Clinical Research Nurse must ensure local policy is implemented to safeguard the wellbeing of their patients and that the research is conducted within ICH Good Clinical Practice.
Bradford Institute for Health Research
The Bradford Institute for Health Research, based at Bradford Teaching Hospitals NHS Foundation Trust, Bradford Royal Infirmary site, was established in 2007 as a unique research partnership between the primary and secondary care NHS Trusts in Bradford and Airedale and the universities of Bradford, Leeds and York. There is a real passion and commitment from the partners of the BIHR to harness the potential for expanding research in Bradford and establish the Bradford NHS community as a national leader in applied health research.

The BIHR has a particular focus on public health research, with major programmes including:

- Born in Bradford – one of the world’s largest public health research projects following the lives of 14,000 families in the city.
- Stroke and elderly care – hosting the regional stroke research network and one of the leading centres for elderly care research in the UK.
- Patient safety – developing innovative solutions to improve the major public health issue of patient safety
- Maternal and child health – a new centre covering obstetric trials, paediatric epidemiology and childhood obesity.

The BIHR has developed a strong track record in applied research and is a national centre of excellence in a number of health priority areas. In 2006 Bradford became the only centre in Yorkshire to win a clinical research network application with the £2 million Yorkshire Stroke Network.

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During 2007-11 researchers in Bradford were successful in winning major National Institute for Health Research (NIHR) applied programme grants worth over £10 million for:

- Stroke rehabilitation,
- Child obesity
- Patient Involvement in Patient Safety
- Delirium prevention
- Cord clamping at delivery
- Patient Quality and Safety (following bid to become a national centre)

The BIHR also hosts the Born in Bradford research programme which has been successful in winning over £7 million in research grants over the last two years.

In 2008 Bradford was one of the biggest winners in the White Rose Health Innovation Partnership awards recognising strengths in wound care research, rehabilitation and obstetrics. Bradford NHS in partnership with the Universities of Leeds and York were successful in winning a £20 million CLAHRC centre, with three of the five themes based on Bradford research programmes.

In 2010 the BIHR became the centre for the new £3 million Yorkshire and Humberside Health Innovation and Education Cluster, driving innovation into practice in key priority areas such as long term conditions, child health and patient safety.

The Institute provides a physical centre for academic and research staff employed by the Trusts and the Universities of Leeds and Bradford and houses a number of these staff. In addition it provides the following facilities for health care professionals in the Trusts:

1. Purpose-designed clinical research facility for all patients involved in commercial and non-commercial clinical trials, supported by high calibre, dedicated research nurses.

A patient being assessed in the Clinical Research Facility

2. A hub for all clinical researchers in Bradford across all disciplines.
3. An Exchange area where researchers can meet and network and share their research ideas and expertise.
4. A formal meeting room for research training and research meetings and seminars
5. A Research Design Service for supporting grant development for clinical staff with new ideas.

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Due to the success of the BIHR in obtaining research grant funding, the BIHR building has been expanded in 2010 to accommodate the BIHR’s growing research workforce along with accommodation for some of its key research partners. This £2 million extension provides accommodation for 70 people and a 21st century research centre for Bradford.

We can offer placement opportunities for students to work with research nurses in some of the BIHR research programmes, and within clinical research within the fields of medicine, surgery and women’s and children’s services.

For further information about our research please visit: [www.bradfordresearch.nhs.uk](http://www.bradfordresearch.nhs.uk)

Contact:
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Sheree Hamburg: 01274 383530 sherree.hamburg@bthft.nhs.uk

*Airedale NHS Foundation Trust*

**Strategic Aims**

In line with the strategic goals and objectives of the Trust and the NHS Operating Framework the aims for Research within Airedale NHS Trust are as follows:

- To improve our research profile within the research community and foster a vibrant research culture within the Trust
- To promote and facilitate research activities across the Trust and establish Research & Development as part of the core business of the Trust
- To develop the workforce to deliver national and local projects
- To engage service users in setting the research agenda at all stages of the research process from inception to dissemination of findings
- To achieve excellence in research and innovation through first class support, training and education

*Research experience for Student Nurses at Airedale Hospital.*

Airedale NHS Trust is actively involved in research across a range of areas; in particular, the specialties of oncology, haematology, diabetes, elderly care, cardiology and stroke, with a high level of recruitment to clinical trials.

Student nurses and newly qualified nurses working on the stroke unit at Airedale are welcome to spend an agreed amount of time working alongside the stroke research nurse covering aspects such as:

- Stroke research trials currently recruiting at Airedale;
- Good Clinical Practice for research;
- How research has influenced stroke management;
- There may also be an opportunity to assist in the recruitment of patients into clinical trials.

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Student Nurses who wish to have a broader experience of research at Airedale can (with the agreement of UoB) take advantage of a bespoke student learning and experience package which will be tailored to the individual requirements of the student nurse. This may involve any or all of the research areas at the Trust i.e. Oncology, Haematology, Stroke and Cardiology. The student would be welcome to spend 1 – 2 days working within the agreed research areas.
Bradford District Care Trust (BDCT)

Our Vision
BDCT provides mental health, learning disability and community services care across Bradford, Airedale and Craven. BDCT’s vision statement includes three elements: “Putting you at the heart of what we do”; “excellence in service delivery; and “continual improvement in the patient experience”. Engaging in high quality research is essential to delivering excellence and improving services. Involving patients and the public in setting the research agenda and in all stages of the research process can ensure that the population we serve remains at the heart of what we do.

Our goals are then:
• to improve mental health, learning disability and primary care community services through research that is high quality, inclusive, locally relevant, and nationally and internationally significant.
• to create a vibrant research culture in BDCT that supports high quality research, reflecting the diversity of the local population and benefiting service users and communities.

These goals are achieved in partnership with:
• National organisations, research networks etc.
• local Trust networks
• academic partners
• strong links with service user and carer groups

What we do
The Trust has a growing team of research staff, from a variety of backgrounds, including nursing, psychotherapy, and research governance, running studies in:
• adult mental health
• child and adolescent mental health
• older peoples’ services
• forensic services
• community nursing

Studies cover a variety of methods including genetics, interviews/observational studies and randomised controlled trials.

What we can offer
Placements can be arranged, following discussions, for those interested in finding out more about any of the above areas.

Contacts:
John Hiley – Senior Clinical Studies Officer, john.hiley@bdct.nhs.uk, 01274 228620
Angela Ross – Research Manager, angela.ross@bdct.nhs.uk, 01274 363149

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Primary Care Research Network (PCRN)

The Primary Care Research Network is part of the National Institute for Health Research Clinical Research Network and is funded by the Department of Health.

What we do:
We are dedicated to providing a world-class infrastructure to conduct clinical research in primary care settings - where the majority of patient/practitioner contacts take place. We work with a wide range of primary care practitioners, such as GPs, dentists, pharmacists and health visitors, and support high-quality research in areas for which primary care has particular responsibility. These include disease prevention, health promotion, screening and early diagnosis, as well as the management of long-term conditions, such as arthritis and heart disease.

Why we do it
Clinical research is, and has always been, fundamental to the work of the NHS. Only by carrying out research into “what works” can we continually improve treatments for patients, and understand how to focus NHS resources where they will be most effective. All the research that we support is driven by the priorities of the NHS and the Department of Health, and informed by the views of patients and their carers.

How we do it:
We provide researchers with practical support they need to make clinical studies happen in a primary care setting in the NHS, so that more research takes, and more patients can take part. The practical support we provide includes:
• Reducing the “red-tape” around setting up a study
• Providing access to the people and facilities needed to carry out research “on the ground”, so research activity does not drain core NHS resources
• Helping researchers to identify suitable NHS sites, and recruit patients to take part in research studies
• Advising researchers on how to make their study “work” in the NHS primary care environment

This practical support is delivered by staff in our eight Local Research Networks which cover the whole of England. Typically, Local Research Network teams include a Network Manager, research support staff from nursing and other health professions or life sciences backgrounds, data managers and administrative staff. These regionally based staff develop in-depth knowledge of local GP practices, health centres, dental practices and other primary care services so that they can involve you in clinical studies that are relevant to you - whether you’re a patient or a practitioner.

The management, development and performance of the Primary Care Research Network are overseen by our Coordinating Centre in London.

There are not currently any placement opportunities available through the PCRN, but if you are interested in their work please contact:

Angela Wray, Research Nurse PCRN (N&Y) E-mail: angela.wray@nyren.co.uk Tel: 07790755971

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Below are some case studies from staff working in research in Bradford and Airedale. These illustrate the diverse nature of research roles within the NHS and the skills and knowledge that these staff bring to their roles.

Christine Kelly:
Lead Diabetes Research Nurse and Lead Nurse- Clinical Research Facility

Christine qualified as a general nurse in 1991 and worked within acute elderly medicine. She started out as a junior staff nurse and progressed to position of junior ward sister.

Over the years, Christine’s interest in diabetes grew and so she looked to become a clinical nurse specialist in diabetes.

In 2001 the opportunity came to work within the diabetes team. A post for diabetes research nurse was advertised. This was a new position for the diabetes department, and enabled Christine to develop research knowledge and skills. This provided the opportunity to work within a dynamic multidisciplinary team consisting of consultant physicians, clinical nurse specialists, dieticians and podiatrists. She soon became involved in setting up both clinical and academic studies working with pharmaceutical companies in phase II to IV clinical trials and the Department of Biomedical Sciences at University of Bradford.

Currently as well as setting up studies, recruitment, retention and managing research projects, Christine’s role has extended and she is also the lead nurse for the Clinical Research Facility. Her responsibilities are to ensure that staff working within the facility adheres to trust policies and procedures and she oversees the day to day running of the facility and helps to ensure the wellbeing of research participants.

Craig Atkinson: Lead Cardiology Research Nurse, Ward 22

I have a BSc in Nursing Studies and have written lots of articles for my personal study. I have worked in cardiology research for the past 5 years, which is interesting and challenging.

I am responsible for a number of cardiology related clinical research trials. My interests are cardiology nursing and teaching.
Bolanle Awote: 
Research Sister, Ward 22 BRI.

I qualified as a nurse in 2005 from Robert Gordon University in Aberdeen with a Bachelor’s Degree in Nursing and completed an MSc in Nursing in 2009.

I now work as a clinical cardiology research nurse on Ward 22 at BRI. I work on research studies offering patients with Acute Coronary Syndrome the opportunity to participate in clinical trials.

Liz Thorp: Quality and Safety Research Nurse, Bradford Institute for Health Research

I qualified as a nurse in 1990 with a diploma in Nursing Studies and since then I worked in different clinical settings in the NHS and private health care. I have worked in the USA and Mexico.

After completing a BSc (Hons) in Health Studies in 1996, I worked as a research nurse at the Twin Research Unit at St Thomas’ Hospital in London. In this role I administered questionnaires, collected blood samples, performed and analysed bone density scans and entered data.

In 1997 I worked as a Research Support Nurse at BTHFT. My job was to help to get more nurses involved in doing research and equipping them with the skills to do this.

I currently work as a Research Nurse at the Yorkshire Quality & Safety Research Group based at the Bradford Institute for Health Research working on a number of patient safety research projects, and I have the opportunity to develop my own research ideas.

Karen Regan: 
Respiratory Research Nurse, Clinical Research Facility BRI

After I qualified I worked a staff nurse then as a Respiratory Nurse Specialist before I became a Respiratory Research Nurse.

I am currently working on six clinical trials, all to do with inhaler medication for COPD. My department is about to start more research into treatments for COPD and asthma. I also have clinical responsibility for patients with severe asthma who receive treatment every 2 weeks.

I have presented posters at the American Thoracic Society and European Respiratory Society, and will be presenting posters in Vienna and San Francisco. I have also been nominated to become a fellow of the Royal Academy of Medical Research.

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### Emma Giddings, Lead Nurse WYCLRN

| Student Nurse | I qualified from the University of York with a Diploma in Nursing and began working as a staff nurse on a medical ward before moving to a part time post on a day unit, both within a district general hospital. During this time I undertook a BSc Hons in Health Policy and was successful in being appointed as a Cancer Research Nurse for the NCRN. This was my first research post and I was able to gain knowledge on conducting clinical trials according to protocol, principles of GCP, the informed consent process, safety reporting and also gained an understanding of research ethics, governance and legislation. I then moved from oncology to renal medicine to take up the post of Senior Research Nurse in a large teaching hospital. This role enabled me to develop management and leadership skills, influence the direction of the research agenda in the unit and set governance standards through education and incorporating into practice any wider research issues. This interest in the NIHR research strategy and an eagerness to address the challenges faced by the research workforce who contribute to this work has led to my current post as Lead Nurse at WYCLRN. |
| New staff nurse | |
| Senior Staff Nurse | |
| Clinical Research Nurse | |
| Senior Research Nurse | |
| Lead Nurse | |

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### Claire Coulson, Quality and Safety Research Nurse

Since qualifying as a nurse I mainly worked within cancer nursing, specialising in chemotherapy initially at Charing Cross Hospital and Hammersmith Hospital in London. My first experience of working in health research was in 2002 where I worked as an Oncology Research Nurse at St George’s Hospital in London. I was responsible for breast, lung and colo-rectal oncology clinical trials. Since then, I have worked as a Research Nurse through the Yorkshire Cancer Research Network and Yorkshire Stroke Research Network, working mainly in clinical trials. My current role is Research Nurse in the Quality and Safety Research Department at Bradford Institute for Health Research.

In 2010 I commenced post graduate study in Health Research. This sparked a real interest in me for developing research ideas and I am currently in the process of completing my own piece of research for my Masters in Health Research. My current position has provided me with many opportunities to develop my research skills. I am involved in and have opportunities to influence the design of the research being undertaken. I am also involved in all aspects of the research process from the development of research ideas through to the dissemination and implementation of research findings. The research team has representatives from psychology, sociology, nursing and medicine. This provides me with fantastic opportunities to learn from other disciplines and to receive expert mentorship and guidance from role models who are established researchers.

My immediate career aspirations are to complete a PhD which will enable me to take my career further in health services research.

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Version 1: April 2012
Hepatology Research


We are Research Nurses within the Bradford Institute of Health Research at Bradford Teaching Hospitals NHS Foundation Trust. We are currently running a clinical research trial that aims to investigate the use of a new treatment for Primary Biliary Cirrhosis (PBC). PBC is a rare chronic condition that can lead to cirrhosis (scarring of the liver) and may progress to liver failure. At present, there is the only one drug that is licensed for the treatment of PBC. This treatment is thought to slow down the progression of the disease, but it does not cure PBC.

The PIANO trial is a clinical trial testing an experimental drug. The experimental drug is an antibody. Antibodies are proteins that help protect the body from infection. The drug used in this trial binds to, and inactivates a specific protein. By stopping this protein working this should reduce inflammation in the liver. The development of specific immunological treatment would be a significant breakthrough in the treatment of PBC. We hope that the development of a new treatment for PBC may improve the health and quality of life of patients with this rare condition. If shown to be effective, this treatment will influence the care for this group of patients and future nursing practice.

The involvement of specialist hepatology research nurses in the clinical and research management of those receiving new treatments is pivotal to ensure that patients receiving new treatments are monitored and cared for appropriately, therefore ensuring the safety of our patients.
Lynn Johnston, Stroke Researcher, Yorkshire Stroke Research Network.

I have been employed by the Yorkshire Stroke Research Network for the last five years, working in the Bradford Hospitals NHS Foundation Trust. My role includes recruiting patients into studies from a portfolio of stroke related research trials. The CLOTS trials have played a large part in my stroke research working life – we are now collaborating on CLOTS 3.

CLOTS 1 was a randomised controlled trial of 2518 patients hospitalised within one week of an acute stroke and immobile. Patients were randomised to routine care with or without thigh length graduated compression stockings. At this point, guidelines were suggesting that stockings should be put on all stroke patients at risk of deep vein thrombosis. Research had shown them to be effective in surgical patients, but the CLOTS investigators believed that those with stroke differ as they can only be treated after becoming immobile.

The study revealed that graduated compression stockings not only fail to prevent deep vein thrombosis after stroke but that they also damage the skin. They yielded only a non-significant 0.5% absolute reduction in deep vein thrombosis; and revealed a fourfold increase in skin ulcers and necrosis among stocking wearers, along with a non-significant increase in lower limb ischaemia compared to those who did not wear compression stockings.

It has been very rewarding to be involved in a study where the results have changed practice, preventing unnecessary harm to patients (and saving nursing time on unnecessary treatment!)

The work goes on with CLOTS 3 – to see whether the use of intermittent pneumatic sleeves can prevent deep vein thrombosis in the same group of stroke patients....

Velcade administration in Relapsed Multiple Myeloma patients
Victoria Drew, Lead Haematology Research Nurse. 01274 383438  victoria.drew@bthft.nhs.uk

Haematology Research at Bradford has been established for many years, and is currently recruiting to 15 trials, with several more in follow-up. One of these trials was a commercially sponsored trial looking at the use of intra venous (IV) versus sub cutaneous (SC) Velcade in patients with relapsed Multiple Myeloma.

Velcade is licensed for use in patients who have relapsed multiple myeloma and it is usually given IV in 4 doses over 2 weeks. This involves cannulating the patient and running saline through whilst administering the Velcade. The patient therefore needs to spend about 30-40 minutes on the day unit, twice a week for 2 weeks for a 5 minute infusion.

In 2009-2011 Johnson and Johnson sponsored a study looking at the potential of SC administration of Velcade. This research investigated the effect that SC administration of Velcade had on the blood plasma levels of the drug, and also overall survival rates for these patients and compared this with the effects of Velcade when administered IV. The results showed there was no difference in the plasma levels of Velcade and the overall survival was comparable between the 2 routes. The side effects were also comparable and the differences in any local inflammation experienced between cannula site and sub cut site were not significant.

Because of this trial, the FDA has now approved Velcade to be given SC, which means patients are on the day unit for less time than if they needed to be cannulated.

More trials in the UK are now adopting the use of SC Velcade, and it is hoped that MHRA and NICE approval will follow, enabling all patients to benefit from SC administration.
## Trial Design, Phases of Clinical Trials

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<thead>
<tr>
<th>Phase</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Early Phase/Phase I Trials</strong></td>
<td>Phase 1 trials are the first test of a drug in humans; this typically involves a small number of participants in a gradual step wise approach, entering patients into dose cohorts, with careful assessment and evaluation before increasing the dose in further subjects. The main aim of such studies is to establish the safety profile, drug metabolism, disposition and tolerability in human subjects, building on existing preclinical data.</td>
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<tr>
<td><strong>Phase II Trials</strong></td>
<td>Phase 2 trials aim to provide further safety information, adverse event management and information on drug activity (efficacy). These trials are normally used to determine dose regimens and obtain further safety data in a larger number of patients.</td>
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<tr>
<td><strong>Phase III Trials</strong></td>
<td>Phase 3 trials are usually large scale comparative studies to look at the risks, benefits and side effects of a drug compared to or in combination with other drugs or placebo.</td>
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<tr>
<td><strong>Phase IV Trials</strong></td>
<td>Phase 4 trials take place once the drug has been shown to be effective and has been granted a licence. These trials aim to find out how well the drug works when used more widely than in clinical trials, the long term risks and benefits and gain more information on the possible side effects and safety of the drug.</td>
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### Guides to make sense of the evidence:


- [http://www.casp-uk.net/](http://www.casp-uk.net/) Critical appraisal tools for different research methods

### Research methods:


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Further resources:

NIHR Clinical Research Network  http://www.crncc.nihr.ac.uk/about_us
NIHR Clinical Research Portfolio  http://crncc.nihr.ac.uk/about_us/processes/portfolio
West Yorkshire CLRN  http://westyorks.crncc.nihr.ac.uk

Useful contacts:

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WYCLRN:

Emma Giddings:  0113 3923765  E.K.Giddings@wyclrn.org.uk
Glossary

ADVERSE REACTION: (Adverse Event.) An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time.

ARM: Any of the treatment groups in a randomised trial. Most randomised trials have two "arms" or treatment groups; but some have three "arms" or more.

CLINICAL TRIAL: A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.

COHORT: In epidemiology, a group of individuals with some characteristics in common.

CSP: Co-ordinated system for gaining permission to conduct research in NHS organisations.

CTIMP: Clinical Trial of an Investigational Medicinal Product. Any investigation in human subjects, other than non-investigational trial, intended to a) discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; b) to identify any adverse reactions to one or more such products or c) to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety or efficacy of those products.

CONTROL: A control is the nature of the control intervention.

CONTROL GROUP: In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment or a placebo.

DOUBLE-BLIND STUDY: A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called double-masked study.

ELIGIBILITY CRITERIA: Summary criteria for participant selection; includes Inclusion and Exclusion criteria. (See Inclusion/Exclusion Criteria)

HYPOTHESIS: A theory or supposition to be tested in a systematic way. Research will provide knowledge and information in order that the hypothesis may be accepted, rejected or further studied.

ICH GCP: International Conference on Harmonisation – Good Clinical Practice. Guidelines to protect the safety of research participants by which all researchers are required to adhere.

INCLUSION/EXCLUSION CRITERIA: The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

Authors:
Angela Grange, Claire Coulson, Emma Giddings, Kelly Young, Paula Sharratt, Lynn Johnston & John Hiley

Version 1: April 2012
INFORMED CONSENT: The process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.

INTERVENTIONS: Primary interventions being studied: types of interventions include Drug, Gene Transfer, Vaccine, Behaviour, Device, or Procedure.

PLACEBO: A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, placebos are often used to assess the effectiveness of the experimental treatment.

PPI: Patient and Public Involvement

RANDOMISATION: A method based on chance by which study participants are assigned to a treatment group. Randomisation minimises the differences among groups by equally distributing people with particular characteristics amongst all the trial arms. The researchers do not have any influence over the allocation of participants into a particular arm of a research study. This helps to minimise bias.

SIDE EFFECTS: Any undesired actions or effects of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects.

SINGLE-BLIND STUDY: A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking; also called single-masked study.

STATISTICAL SIGNIFICANCE: The probability that an event or difference occurred by chance alone. Statistical significance is often represented by a ‘p value’ or ‘confidence interval’. (In clinical trials, the level of statistical significance or confidence that the researcher is that the result did not occur by chance depends on the number of participants studied and the observations made, as well as the magnitude of any differences observed.)

TOXICITY: An adverse effect produced by a drug that is detrimental to the participant’s health. The level of toxicity associated with a drug will vary depending on the condition which the drug is used to treat.

Glossary Sources:


CenterWatch, Inc. Patient Resources: Glossary.

ECRI (formerly the Emergency Care Research Institute).

Eli Lilly and Company. Lilly Clinical Trials Glossary.
Dear Student,

Thank you for taking the time to complete this questionnaire. This is the first of two questionnaires that you will receive asking you about your views regarding your research placement. Your opinion is important to us, as it will help us to improve the quality of research placements in the future.

Please read all the questions carefully and answer each of them. There is no right or wrong response. Any information you provide will not be shared with anyone and you will not be identified under any circumstances. To maintain confidentiality and to ensure that we can match up your questionnaires, please complete the personal code as indicated below.

Please return your completed questionnaire in the envelope provided to the research professional who you are working with on your research placement. They will return the questionnaire to us.

If you have any questions please contact:

Angela Grange, Lead Nurse, Clinical Quality & Research/ Trust Lead, Innovation Quality and Safety Research
Bradford Institute for Health Research
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
BD9 6RJ

Telephone: 01274386890
E-mail: angela.grange@bthft.nhs.uk
Please enter your personal code

Date of birth (DD/MM/YY)          Initials

**Time 1**

**Date:** __________________

1. **Which educational institution do you attend?**

__________________________________________________________________________

2. **What date did you commence your training?**

__________________________________________________________________________

3. **Gender:**  Male / Female

4. **Has research been taught as part of your training programme so far?**  Yes/ No

If yes, please complete the table below:

<table>
<thead>
<tr>
<th>Name of the module / training</th>
<th>Organisation that conducted the education</th>
<th>Year attended</th>
</tr>
</thead>
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</tbody>
</table>
5. Which clinical area is your research placement attached to?

________________________________________________________________________

Please tell us in the space below what you are expecting to achieve from your research placement:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Below are a number of questions that ask you to think about research in the NHS and putting research into practice. Please read each item and circle one response that best reflects your opinion.

6. I feel confident to question an area of clinical practice:

<table>
<thead>
<tr>
<th>Strongly disagree</th>
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<th>Neither agree or disagree</th>
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7. I understand the research process that provides the evidence for clinical care:

<table>
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8. I know how to go about searching for evidence to investigate a question about clinical practice:

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</table>
10. I understand how the West Yorkshire Comprehensive Local Research Network supports research in the NHS in West Yorkshire:

<table>
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THANK YOU

FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.

WE HOPE THAT YOU FIND YOUR RESEARCH PLACEMENT INTERESTING AND WORTHWHILE.
Dear Student,

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Version 1: April 2012
Please enter your personal code

Date of birth  (DD/MM/YY)  Initials

**Time 2**

Date: ________________________

11. How did you arrange your research placement?

__________________________________________________________________________________

12. How easy did you find it to arrange your research placement?

<table>
<thead>
<tr>
<th>Very difficult</th>
<th>Difficult</th>
<th>Neither</th>
<th>Easy</th>
<th>Very easy</th>
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13. How long was your research placement?

______________________________________________________________________________

14. Did your research placement meet your expectations?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>A little</th>
<th>Somewhat</th>
<th>Very much so</th>
<th>It exceeded my expectations</th>
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15. Please tell us in the space below four research activities that you observed or experienced during your research placement:

1. ____________________________________________________________
2. ____________________________________________________________
3. ____________________________________________________________
4. ____________________________________________________________

5. Would you recommend a research placement to your colleagues? Yes / No

6. Do you have any suggestions for improvements to the research placements in Bradford and Airedale?

__________________________________________________________________________________
__________________________________________________________________________________
__________________________________________________________________________________
__________________________________________________________________________________

Below are a number of items that ask you to think about research in the NHS and putting research into practice. Please read each item and circle one response that best reflects your opinion.

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