"They said if I wasn’t on the diabetes trial then I wouldn’t be here now. It would have been too late."
Welcome

from the Interim Chief Operating Officer

Welcome to our new-look e-newsletter for the CRN West of England. 2016/17 was a successful year for all NIHR staff locally recruiting 26,801 participants to NIHR research studies (a 28% increase from 2015/16) in 30 different specialties. Thank you to all the clinical research teams and R&I departments across the network who have worked hard to ensure that research opportunities are available to patients wherever they are cared for.

For 2017/18 equity of access for research for participants remains a priority. Within the LCRN we are working hard to explore new ways of working with all stakeholders to facilitate research taking place where there is the most need. This will ensure access to the latest treatments and health professionals have the evidence required to improve health outcomes for patients.

Our newsletters will focus on the key areas of the LCRN business and the priorities of the annual plan, complemented by your news and updates. I hope you enjoy the first edition.

Thank you so much for all your continued hard work.

Best wishes

Dr Sue Taylor, Interim Chief Operating Officer

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A huge thank you to all the staff and research participants, as well as the steering committee, who delivered and responded to the Patient Research Experience Survey 2017.

Overall, the results show that participants in research across the West of England have had an overwhelmingly positive experience of taking part in research and would consider taking part in other studies if offered the chance. Many respondents commented about the opportunity to improve the health of others and the chance to make a difference as being their main reasons for taking part in research.

The full report is almost finalised and will be distributed to our main PRES contacts very soon.

Sharon Tovey, research nurse at North Bristol NHS Trust and leader of the LCRN diabetes project, organised an event to ‘bring together all those working in diabetes with an interest in research’ with an aim to improve collaborative working across primary and secondary care.

The event was packed with presentations on best practice, by representatives from commercial companies such as AstraZeneca, NovoNordisk, Sanofi and Servier and case studies from local Trusts.

More recently, in late May, there was a consultation group meeting with patients to discuss the promotion of research studies resulting in valuable feedback and further actions.

Congratulations to the Royal United Hospital, Bath, which is the first site for study ‘Retrospective-prospective cohort study to observe Safinamide safety’ to recruit world-wide. The study is purely observational and designed to observe male and female patients being treated for Parkinson’s Disease. Patients with mental health conditions such as psychosis, bipolar disorder, depression and anxiety are of particular interest.

Principal Investigator Dr Emily Henderson said: “We were delighted to have set up the Royal United Hospitals Foundation Trust in Bath as the first UK site for this important trial of a new drug in Parkinson’s disease. Having recruited the first participant in the UK we are looking to recruit more patients who are starting this medication called safinimide so that we can closely monitor their response to this new treatment.”

Also, congratulations to the team at University Hospitals Bristol, who were the first to recruit globally for ‘A Study of CYP-001 for the Treatment of Steroid-Resistant Acute Graft Versus Host Disease’. As the research study summary states: ‘Allogeneic (donor) stem cell transplantation is a potentially curative treatment for patients with cancer and bone marrow failure although is associated with significant side effects. Acute graft versus host disease (aGvHD) is the result of the donor immune system, mediated by lymphocytes (inflammatory white blood cells), attacking the recipient tissues and is one of the most serious complications of allogeneic transplantation. This typically occurs within the first 3 months following transplant and affects up to two thirds of transplant recipients. Significant aGvHD is treated with corticosteroids although up to half of patients require subsequent lines therapy. Currently available treatments for steroid refractory aGvHD are often ineffective and there is no standard of care and the mortality for patients with resistant aGvHD is high. Mesenchymal Stem Cells (MSC) are self-renewing cells that can be derived from a range of tissues including bone marrow and fat. They are able to inhibit a range of inflammatory cells including lymphocytes, natural killer cells and dendritic cells, on which basis they have been investigated as a possible treatment for aGvHD. Results of previous studies using MSC in aGvHD have been mixed although this is likely to be explained in part by the different techniques used for isolation of MSC which could impact on their efficacy. This study is a multi-centre, open label, dose escalation study to assess the safety, tolerability and efficacy of two infusions of CYP-001, in adults who have steroid-resistant GvHD.’

Dr James Griffin, Principal Investigator said: “Cellular therapies are an exciting area of research in haematological malignancy and BMT. This trial is an excellent example of working with industry, NHS Blood and Transplant and multiple areas within the hospital to ensure groundbreaking treatment can be safely delivered to our patients.”

Collaboration for diabetes teams

Sharon Tovey, research nurse at North Bristol NHS Trust and leader of the LCRN diabetes project, organised an event to ‘bring together all those working in diabetes with an interest in research’ with an aim to improve collaborative working across primary and secondary care.

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More recently, in late May, there was a consultation group meeting with patients to discuss the promotion of research studies resulting in valuable feedback and further actions.
It’s the most clinical day of the year...

Trusts across the West of England made this International Clinical Trials Day 2017 a great success. There was flash mob disco dancing, I AM RESEARCH thank you cakes, the chance for children to ‘take blood’ and watch it being spun, a coach visiting the people of Cheltenham to promote research and so, so much more.

International Clinical Trials Day commemorates the first randomized clinical trial by James Lind. On 20 May 1747 he started a trial to ascertain what treatment would best cure scurvy, on board a ship. The event is celebrated worldwide by primary and secondary healthcare organisations and is an ideal opportunity to promote the value of clinical research to the general public and colleagues. In the UK, every Network across England participates, with Trusts and primary care organisations holding events ranging from promotional stands in reception areas to film screenings and debates.

The Clinical Trials Gateway

This year, the posters, postcards, banners and bunting provided by NIHR Central promoted the web address for the Clinical Trials Gateway. This is a database holding details of research studies. Members of the public can search by specialty and/or location to discover the clinical trials that are recruiting near them and to sign up for the projects they are interested in. Signing up does not guarantee being able to take part in a trial, but it does mean that researchers are aware of potential participants.

It’s still OK to Ask...

The campaign slogan and message for the past four years was ‘It’s OK to Ask’ about research opportunities. This year there is a new campaign: ‘I AM RESEARCH’. The idea behind the new slogan is that while evidence-based research is of course rigorous and scientific, it is people who make research happen: public participants for their own enhanced care and their altruism in making the future better for others and clinical trial teams, from non-clinical staff to research nurses to chief investigators.

Across the West of England

There was so much activity across the West of England it’s not been possible to include everything here so please look through this short presentation to get an idea of some of what happened: https://spark.adobe.com/page/IFfLSKZuNmkxa/

A summary of work across the CRN as a whole is being developed and we’ll tweet the report as soon as it’s released - follow us on @crnwestengland

The national campaign

The national team’s events included a NIHR CRN Research Nurse blog and a case study from the previous winner of Nursing Times Clinical Research Nurse Award in May’s Nursing Times. A MOOC: ‘Improving Healthcare Through Clinical Research’ started on 22 May and on 18 May Allan Gaw’s ‘Business of Discovery’ podcast had an International Clinical Trials Day edition with Jonathan Sheffield, available at soundcloud.com/allangaw
Join Dementia Research

Join Dementia Research in numbers

- **28,465** total volunteers
- **52,174** screenings
- **7,502** participants that have enrolled in studies to date
- **26%** of volunteers have participated in a study
- **151** studies have recruited
- **103** studies currently open to recruitment
- **806** trained researchers using the service
- **171** NHS, University & commercial sites have used the system

In May 2017, the West of England was the third best LCRN for recruitment to Join Dementia Research in England and Scotland. A spreadsheet of LCRN recruitment performance is available - please email sarah.lynch@nihr.ac.uk to receive it.

Business Intelligence

Mike Lacey, the LCRN Business Intelligence Manager, says: “I am pleased to announce that the CRN West of England ODP application is now live on the NIHR ODP Access Point that can be reached via the following URL: [https://odp.nihr.ac.uk](https://odp.nihr.ac.uk)

All staff funded to work on NIHR Portfolio studies are entitled to an NIHR account that will allow access to the ODP app; alternatively, individuals may sign up using a non-NIHR e-mail address at the link above. There are multiple files hosted on the Access Point - the West of England app is entitled “CRN WE Portfolio ODP.qvw”.

The app is refreshed with data from CPMS every night and therefore reflects the latest recruitment activity reported to the NIHR. Sheets in the CRN WE app allow users to analyse national performance (comparison of LCRN performance and activity-based funding) and local performance by partner organisation and specialty in financial year 2016/17. Additional sheets allow users to drill down into performance of individual studies across England and to review the latest studies added to the NIHR Portfolio. A short guide to each of these sheets will be published shortly.

Training in the use of ODP can be arranged either at University Hospitals Bristol or on site for small groups. It is best delivered in a Computer Assisted Learning (CAL) suite where participants have access to their own PC that is connected to the Internet. Please contact either Ifan Jones or myself to discuss requirements further.”

The LCRN is always keen to receive feedback from users - if you would like to contact us regarding the app with either bug reports or suggestions for future development/features, please e-mail: BIU.WestEngland@nihr.ac.uk in the first instance.
"One time they discovered I had something wrong with my blood," says Mel Reynolds at his home in north Bristol. "As I was on the diabetes trial, at the hospital, they used to take my blood and blood pressure and weight every three months. Whereas down the doctors it was once a year. When they analysed my blood they discovered I had cancer. And I'd had no symptoms whatsoever. They said if I wasn't on the diabetes trial I wouldn't be here now because it would have been too late."

Mel, 70, decided to take part in the LEADER clinical trial for diabetes six years ago, after being approached by diabetes research nurse Sharon Tovey. It was a commercial trial by the Novo Nordisk company, running in North Bristol NHS Trust. It was a multicentre, international, randomised, double-blind, placebo-controlled trial to examine the long-term effects of liraglutide, a drug to treat Type 2 diabetes. Though the medicine was already in use by the NHS, the US Food and Drug Administration (FDA) required extra clinical trials to ensure that its use would not cause risks to multi-morbidity patients with cardiovascular conditions. Mel was keen on participating in the trial, his wife Jane was not so sure.

"I was dead against it," says Jane, 55. "I just didn't know what he was putting into his body. They said it was safe and had already gone through all these other trials but you still wonder if it is, so I was worried. But when we discussed it Mel said that it might help him live for another five years [that was the length of the trial] and we decided that was worth it. And you know, the care that Mel had received even before we knew he had diabetes, all those tests he went through then, the care was second to none. So it made sense."

Around 700 people a day are diagnosed with...
diabetes - the equivalent of one person every two minutes. In the UK there are an estimated 4.5 million people living with diabetes – 10% with Type 1 and 90% with Type 2. Diabetes can increase the risk of heart disease, kidney disease, eye disease and potentially dementia. Type 2 diabetes is treated with a healthy diet and increased physical activity. In addition to this, medication and/or insulin are often required.

Clinical research trials, funded by the National Institute of Health Research (NIHR) and facilitated by the Clinical Research Network (CRN), support the NHS in helping patients by ensuring that their treatments are evidence-based and cost-effective. Trials aren’t always for drugs – participants can be asked to answer questionnaires or take part in online interviews rather than trial new drugs. Many patients feel their overall care is enhanced by taking part.

“Trials aren’t always for drugs – participants can be asked to answer questionnaires or take part in online interviews rather than trial new drugs.”

“Mel was overweight at the start of the trial but within six months everything had changed,” says Jane. “He was never a big drinker but he never even fancied a drink.”

“Two years off the trial and I haven’t drunk anything. I’m just not interested. When we’re off on holiday and the weather’s nice and everyone’s sat outside the pub it just doesn’t interest me; I just don’t want to drink,” confirms Mel.

Sharon Tovey, the research nurse coordinating the trial, explains. “The drug doesn’t stop people wanting alcohol necessarily. People with Type 2 diabetes have a lower level of GLP1 enzyme in their duodenum. The enzyme makes people feel fuller for longer by slowing down the gut emptying, so people probably don’t want to drink pints anymore because they feel too full. The drug also affects the satiety centre of the brain which contributes to ‘feeling’ fuller. It helps the pancreas produce insulin only when the blood sugars are high. That’s a real benefit of this drug; it means there is much lesser risk of having a hypo (blood glucose less than 4).”

Sharon’s expertise and the sharing of her knowledge really helped the Reynolds manage the condition. “We were privy to more information than what we had before,” says Jane. “Sharon ran classes every six weeks and none of us knew who was on the drug and who wasn’t. It was brilliant because we learned so much. We had such a lot of information. When Mel was first diagnosed with diabetes, I got books and I tried to find out as much as I could but I just couldn’t remember it all. It’s not always that straightforward. But at this group, they explained why we had to eat differently and how it all worked, and what the medicines were doing, and it really helped. We started to understand it more. And sometimes, when you see your doctor you only have ten minutes and you forget any questions you have but at the group you could ask as much as you wanted, and you never felt silly. And when Sharon said she was at the end of the phone she meant it – we could ring at any time and she was always there to help. It was brilliant.”

It was about three months into the trial that Mel’s regular tests revealed something was amiss.

“They called me in on 27 December,” Mel says. “And I said to Jane – I could sense it – I said, ‘I think there’s something wrong.’” “And I told him he was being silly,” Jane adds, “but then it was Sharon’s face when we went in, and they said they’d found cancer.”

Mel had two tumours, both on his liver. Two weeks after his diagnosis, the tumours were removed at the BRI. (“There was excellent communication with the NBT team,” says Sharon.). The cancer was found as a result of the trial routine blood tests (his amalayse and lipase were elevated which suggested there was a problem, and prompted a liver scan) a test that would not have been completed in standard clinical care. And now he has been cancer-free for five years, Mel will be signing up for his next trial at the hospital. “I always push him to do anything that’s going now,” laughs Jane.

“We owe more than you’ll ever know,” continues Jane. “I recommend taking part in research trials to everybody. If people could just put their fears aside... I’d shout it from the roof-tops; I’d have an air balloon advertising if I could. Me and the boys will be forever grateful.”

“I recommend taking part in research trials to everybody. If people could just put their fears aside... I’d shout it from the roof-tops; I’d have an air balloon advertising if I could.”

“Apart from marry ing my wife”, says Mel, “taking part in research was probably the best thing I’ve ever done.”
Primary care updates

Research network events generate top tips

Research active and research curious representatives from GP practices across the West of England came together in February to learn more about the benefits of being involved in clinical research.

At each event we asked attendees to provide their top tips for being a research-active practice. These can be found on the primary care website.

If you have questions about any aspect of Primary Care research check the FAQs section of our Primary Care website https://sites.google.com/a/nihr.ac.uk/crnwestofenglandprimarycare/about-us – and if your question isn’t answered there please call the team on 0117 3421375.

Clinical Practice Research Datalink (CPRD)

From the CPRD:
The CPRD is a body funded by the MHRA and NIHR which has been providing anonymised records for public health research for over 25 years. As examples, CPRD research directly informs NICE guidelines on cancer in primary care, has proved the safety of the pertussis vaccine in pregnancy, and highlights the need for patients with long term conditions to receive the winter flu jab as a means of lowering hospital admissions.

As part of our GP engagement strategy, we are keen to target Research Champions/Leads from specific CCGs, especially those with large numbers of EMIS practices. Currently Bristol CCG has 50 GPs using EMIS and Vision, of whom 13 contribute to CPRD. There are many advantages to GP practices within your CCG joining CPRD as listed on the CPRD flyer. These benefits include GPs being given the opportunity to participate in clinical trials and take part in quality improvement projects such as the one CPRD are currently running with the RCGP. Joining CPRD is simple, free, and going forward takes no practice time unless the practice participates in clinical trials – if they do they are remunerated for this.

To see the flyer in full, please visit the primary care website where you can see it in the latest news items. We will also tweet it again, so follow us on @crnwestengland to see the link.

Primary Care Communities of Practice meeting

In September 2017, the CRN West of England are holding a Communities of Practice meeting for LCRNs in the South of England.

Representatives will be coming from South West Peninsula, Wessex, Thames Valley and Kent, Surrey and Sussex.

The aim of the meeting is to improve cross-CRN working and speed up the process of sharing studies across regions.

Public Health England survey request

Public Health England (PHE), in collaboration with the RCGP, would like to invite you take part in a survey to identify which conditions you would like to see more evidence for management in your daily clinical practice. The survey takes seven minutes to complete and your response will be used to determine where research is needed and to inform guidance development. On completion, you will have the opportunity to enter your details into a draw to win one of four sets of £50 John Lewis vouchers. You can access the survey here https://surveys.phe.org.uk/GPsurvey
Study success

Last minute turnaround beats target

Genetic Study of Age Related Hearing Impairment was a study open at University Hospitals NHS Foundation Trust. It is a genetics study which aimed to understand the genetic influences of age related hearing loss which involved a questionnaire and a blood sample. The study opened in August 2015 and had a recruitment target of 30 people.

The study had some barriers to recruitment including a PI that was new to research and recruitment taking place at a location different to the study team location. This required the research nurse to have to walk up and down a very steep hill, for every potential participant, sometimes multiple times a day.

There was an extension on the study until the end of January 2017 and the team knew they needed to improve their recruitment. Amanda Hall, PI, spent a lot of time with the study team and audiologists with the aim to improve recruitment. The team managed to recruit 15 participants in the final month and 31 participants in total before the closing date, meaning they achieved their recruitment to time and target goal. This was all down to the huge efforts of Amanda and the research nurse Louise Flintoff.

Amanda Hall, PI, says: “We improved our communication and team working over the course of the study, which meant that by the last few months of the study we had a good communication system in place, had identified the barriers to recruitment and had worked out what was effective and what was not. Monthly early morning meetings did the trick. In addition, Louise and the research nurse team were very flexible and did a lot of walking up and down the hill at even the hint of a potential recruit, and Andrew and the Audiology team worked really hard to identify potential participants. Our success was definitely all down to the team!”
Curious about Twitter but don’t know where to start?

On 18 July 2017 CLAHRC West are running a great training session at Whitefriars, Lewins Mead, Bristol called ‘How to win at Twitter’

Twitter is an increasingly important platform for building your reputation, finding collaborators and discovering what other people are doing.

Please note that spaces for this course are limited to 12. The course is free to attend. Please visit the CLAHRC website and complete the application form.

Congratulations to Dr Kaitlin Wade

Great news for Dr Wade, who was awarded the Cancer Research UK ‘Rising Star in Public Engagement’ Award on 20 June. Dr Wade (pictured above, second from left) is a Research Associate in Genetic Epidemiology at the School for Social and Community Medicine. The award ‘recognises an individual who has demonstrated exceptional commitment to stimulating enthusiasm and interest in cancer research among the general public’

Professor Richard Martin said: “Particular favourites of Kaitlin’s projects were her Guess Who-style board game to explain population-level genetic cancer risk, and an interactive art installation at Green Man Festival through which festival visitors took on the role of epidemiologists to sort through ribbons of genetic traits over the whole weekend. Kaitlin really is a rising star in research engagement, constantly pushing the boundaries of our engagement offering through her enthusiasm and innovative ideas. Many congratulations Kaitlin!”

See more information, including films with the winners, here.

Congratulations to Professor Deborah Lawlor

Deborah Lawlor is Professor of Epidemiology at the University of Bristol, and was awarded a CBE in the Birthday Honours 2017.

Professor Lawlor and has worked on ALSPAC (the Avon Longitudinal Study of Parents and Children) among many more projects. To see her profile including her latest work see this link: www.bris.ac.uk/social-community-medicine/people/debbie-a-lawlor/index.html

Congratulations!
The NIHR Clinical Research Network supports the development, set-up and delivery of high quality research in England. We provide a range of services across the delivery pathway that will help study feasibility, set-up and delivery to time and target. These are provided through six components:
1. Early contact and engagement
2. Early feedback
3. Site identification
4. Study delivery assessment
5. Effective study Start-up

CRN West of England work together with our Partner Organisations to provide this support to researchers in the region.

The Study Support Service is available for all studies eligible for NIHR support, regardless of location, study type, study size, therapy or research area. Whether your study is medical, diagnostic, pharmaceutical, or bio-tech we can help.

The diagram of the Study Life Cycle (see right) shows the different stages of each study and what we offer at each stage. If you need some advice or help with any aspect of your study, please call Tom Haynes, Study Support Service Facilitator, on 0117 3421378 or email studysupport.westengland@nihr.ac.uk

There’s also a ‘Top Tips for NIHR CRN Portfolio Inclusion’ now published on the CRN West of England website.
**Workforce development**

A key principle of good research in health and social care is that everyone involved is qualified to carry out their responsibilities and duties by education, training and experience.

Deciding which staff should attend the Good Clinical Practice (GCP) training can be difficult. Of course Chief and Principal Investigators want a knowledgeable team to ensure the success of a study but sometimes the standard GCP course is too much, sometimes it’s not enough. As such, the NIHR have worked to create a Delegation and Training Decision Aid designed to help CIs and PIs when making their training decisions at the start of studies.

The Aid has been developed with involvement of a range of stakeholders, including the MHRA, senior researchers and frontline research delivery staff in a range of settings. The Aid (above) can been seen full-size at www.nihr.ac.uk/westengland website.

**New training programme**

Paula Tacchi is now Workforce Development Lead and is working on a number of new initiatives, such as an improved course structure with less content overlap and a fully Trust customisable Induction Handbook for new staff. These publications are being finalised and will be released soon - follow our Twitter account to be the first to know when @crnwestengland

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<tr>
<th>Course title and facilitator(s)</th>
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<tr>
<td><strong>Next steps in Clinical Research</strong></td>
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<td>Good Clinical Practice Refresher</td>
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<td><strong>Introduction to Valid Informed Consent in Clinical Research</strong></td>
<td>22 September 2017</td>
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<td><strong>Introduction to Good Clinical Practice</strong></td>
<td>9 October 2017</td>
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<td><strong>Next steps in clinical research</strong></td>
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For further information or to book a place please contact Donna Burnham, Network Administrator, on 0117 342 1376 or email donna.burnham@nihr.ac.uk