



Joint Research Management Office

Research News Bulletin

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Research headlines

Research Matters: changing lives in East London and beyond

In celebration of International Clinical Trials Day 2016, Barts Health NHS Trust and Queen Mary University of London (QMUL) and Barts and The London School of Medicine and Dentistry will be hosting an afternoon of talks from leading academics, clinicians, patients and others, presenting the very best examples of local healthcare research and development.

The event will be held on **Tuesday 24 May, 4.30-6pm** in the Perrin Lecture
Theatre, Blizard Building, Whitechapel

campus and is open to all staff and students to attend.

Come along and find out about some of the latest developments in research at Barts Health and Barts and the London Medical School. There will be a reception following the presentations, providing an opportunity to network and ask our speakers any questions you may have. It promises to be a stimulating and entertaining occasion.

Confirmed speakers include:

- Dr Shanti Vijayaraghavan,
 Consultant Physician with an
 interest in Diabetes and
 Endocrinology on 'DAWN',
 'DREAMS' and beyond developing
 virtual consultations at Barts Health,
 demonstrating how big change often
 begins with very small steps.
- Jo Morgan, Associate Director, CAG Research Development - 'mythbusting' pharma-led research and the development of new drugs and devices for the benefit of our patients.
- Members of Trials Connect project with Dr David Collier, Research Fellow and Joint Clinical Director of the William Harvey Research Institute Clinical Research Centre, talking about their clinical trials experience and why they continue to get involved in healthcare research.
- Dr Johann Grundlingh, Consultant in Emergency Medicine and Intensive Care, on the Valsalva Manoeuvre and developing intellectual property.

To reserve your place, please visit: www.research-matters.eventbrite.co.uk

HRA Approval: the new research application process

HRA Approval is now the process for applying for approvals for all research projects in the NHS led from England.

Researchers still need to work with the JRMO to set up all Barts Health and QMUL sponsored studies. *In many respects this is a case of new systems and some new processes but very much business as usual!*

HRA Approval covers both HRA Assessment and NHS REC review (where REC review is required), removing the need for separate REC and R&D application forms. If you have already started preparing applications in IRAS but not yet submitted, you can easily convert your separate forms to a combined IRAS form. Check the guidance in IRAS for details.

Any studies led from Northern Ireland, Scotland or Wales continue to apply using the existing systems in each nation. If there are English sites in the study, the national R&D coordinating function of the lead nation will share information with the HRA Assessment team, who can issue HRA Approval for English sites and thereby retain existing compatibility arrangements.

The ethical review of all studies will continue to be undertaken in accordance with the UK Standard Operating procedures.

The old CSP system has closed but studies that were being set up when CSP closed can continue to be processed through the CSP Module following CSP 'inflight' business processes. During this time users can continue to log into the CSP module as usual.

Applicants should review the information on the HRA website and check the updates to IRAS.

Local Clinical Research Networks are working with Chief Investigators, Sponsors, researchers and HRA to ensure that all studies are managed appropriately through this changeover period.

If you have any questions please contact the CSP helpdesk at crncc.csp@nihr.ac.uk or the HRA Approval queries contact at hra.approval@nhs.net

Further information can be found on the JRMO's website and on the HRA website including Frequently Asked Questions.

Any questions relating to local implementation should be directed to Liz Clough, R&D Governance Operations Manager in the JRMO: elizabeth.clough@bartshealth.nhs.uk or tel: 020 7882 7275

Opportunities to influence health research in the UK

NIHR research programme boards and panels prioritise important research questions for NIHR commissioning, and make funding recommendations on project applications.

The NIHR are looking for additional expertise for the boards or panels in a variety of areas, including the following programmes:

- Efficacy and Mechanism Evaluation (EME) Programme
- Health Services and Delivery Research (HS&DR) Programme
- Health Technology Assessment (HTA) Programme
- Public Health Research (PHR) Programme

Applications close at **1pm on 25 April 2016**. For details and more information on how to apply please visit the NIHR website here

HSJ Clinical Research Impact Awards 2016

Clinical research is the way that clinicians gather evidence about new treatments, in order to improve patient care in the NHS. Most NHS organisations are involved in research, but there is a national drive to increase the number of opportunities for patients to take part in high-quality research studies.

This prestigious national award is now in its sixth year, and provides an opportunity to recognise and reward the inspirational work that is taking place across the NHS to make clinical research a core activity.

The HSJ Clinical Research Impact Award 2016 is now open for entries. The award is sponsored by the NIHR Clinical Research Network. It is presented to an NHS organisation that has gone the extra mile to embed clinical research as core business and harness the outcomes of clinical research to improve services and treatments for its patients.

Further information including entry criteria is available on the <u>HSJ website</u>.

The closing date for entries is **3 June 2016.**

New JRMO SOPs published

The JRMO has recently published a number of new Standard Operating Procedures. These are:

SOP 26a Pharmacovigilence reporting for CTIMPs with associated documents:

- AE flow chart
- SAE form
- NRES report
- DSUR template
- BH/ QMUL pregnancy reporting/ follow-up form

SOP 26b Safety reporting for non- CTIMPs with associated documents

- Flow chart
- SAE form

SOP 28 Monitoring with associated documents:

- Template monitoring form (CTIMP)
- ISF, TMF, Single site (combined ISF-TMF), Pharmacy, Lab, SDV and Central facility

Monitoring forms, Concise close out visit forms:

- Site, Pharmacy, and Lab
- Site visit log
- Monitoring guidelines
- Quarterly monitoring report template

SOP 38a Use of computerised equipment in research projects

SOP 42b Pharmacy involvement in hosted studies

SOP 45 Essential documentation and Trial Master File (TMF) with associated documents:

- TMF checklist template
- TMF site sections checklist template
- ISF checklist template
- pharmacy site file checklist template
- enrolment log
- site delegation log
- co-ordinating team delegation log
- protocol version control log
- PIS, ICF and GP letter version control log
- amendment log
- file note
- file note log
- trial specific training log
- deviation log

SOP 46 Site selection, initiation and activation and associated documents:

- Site level feasibility assessment guidance
- JRMO SIV checklist template
- JRMO SIV presentation template

SOP 47 Trial committees and associated documents:

- Guidelines for committee charter
- Example charter
- Competing interests form

A full set of SOPs can be found on the JRMO website here.

News from our CRN

CPMS goes live: The NIHR Central Portfolio Management System (CPMS) went live on Thursday 31 March. The system has now replaced the UK CRN Portfolio Database, Industry Application Gateway and Study Tracker. To find out more click here.

CPMS surgery webinars - sign up to a session: The CRN has arranged a series of CPMS surgeries that we're delivering by webinar, each Thursday up to mid-May. These are designed for its virtual Business intelligence Unit, Industry Operation Managers and Research Delivery Managers. To find out more click here.

HRA Approvals and NIHR Metrics: NIHR has issued an 'Update on Performance in the Initiation of Clinical Research in Relation to the HRA Approval' alongside their regular Q3 report and minimum data set. All of the documents including the policy statement are available on the NIHR website. In addition, a webinar which

explains NIHR metrics in more detail is available via the CRN website.

NIHR CRN processes for HRA Approval – a re-recorded webinar now available: CRN publicised this webinar in March, but we had a few technical issues with the recording. If you had a listen and struggled to hear the content, then please try again. We've re-recorded with much improved sound quality. To find out more please click here.

Focus on the Future Seminar: The CRN Coordinating Centre recently hosted a Workforce Development Seminar entitled 'Focus on the Future'. The seminar explored how we could continue developing the research workforce in response to the ongoing changes in clinical research and the NHS landscape. To find out more please click here.

Costing and contracting deadlines

It is never a good idea to leave applications for costings or funding input to the last minute. All types of research grant applications and contracts for both Barts Health NHS Trust and Queen Mary University of London need to be costed or agreed by the Joint Research Management Office (JRMO) before submission. This includes outline applications.

To avoid disappointment, all applications that require costing *must* be submitted to the JRMO *at least* one week before the submission deadline. The JRMO can also help with other process aspects of the application preparation – for contact details please click here.

Local research update

Whipps Cross research award

Each year the Medical Education & Research Trust at Whipps Cross University Hospital provide an award to support research projects to be undertaken at Barts Health that will impact on patients within the Waltham Forest area, and beyond.

This year the Trustees were pleased to offer the award to midwife, Adele Hamilton. Her project will explore the perceptions and experiences of a particular dietary intervention in pregnant women with metabolic risk factors as well as the attitudes of women's partners and healthcare professionals who manage them. The objective will be to determine

the barriers to uptake a dietary intervention.

This prize is aimed primarily at doctors but applications from other clinical staff (AHPs or nurses) and non-medical staff are welcome if they can demonstrate a substantial amount of clinician involvement in the study.

The main criterion for the award are that the proposed study must have the potential to benefit patient care within the Waltham Forest area; it must be an original piece of research of sound scientific quality; have a robust methodology; be realistic in terms of timescale, resources available and funding; be relevant to clinical practice; and have potential to be completed within one year.

£1.2m awarded for research into young adult sudden death

QMUL has been awarded £1.2 million funding by British Heart Foundation for vital research into myocarditis. New work to diagnose and cure a disease which can cause sudden cardiac death in young adults is being carried out at Queen Mary University of London, thanks to research funding from the British Heart Foundation (BHF). The charity has awarded grants of £1.2 million as part of the appointment of Professor Federica Marelli-Berg, from QMUL's William Harvey Research Institute, as BHF Professor of Cardiovascular Science.

The disease, myocarditis, occurs when the heart muscle becomes inflamed and is often caused as a result of infection by common viruses. Around 20 per cent of people with myocarditis go on to develop heart failure, which in severe cases can result in the person needing a heart transplant.

Professor Marelli-Berg is now leading research into the disease, which has, so far, proven difficult to diagnose and treat. This is because, although the dangerous inflammation of the heart muscle seen in the disease is known to be caused by certain types of white blood cells, called T-cells, researchers do not yet know exactly how this process occurs. To find out more about BHF research please click here.

Common antimalarial drug could be used to treat major injury

A common anti-malarial drug Artesunate could be used to reduce organ failure following injury, according to an early study in rats led by QMUL.

The repurposing of the affordable and safe drug could help save the lives of major trauma patients, and the promising results have already led to human clinical trials being planned for this year, supported by the Health Innovation Challenge Fund.

Trauma is a leading cause of death with five million victims a year. About 40 per cent of trauma deaths are due to hemorrhagic shock, which is when severe blood loss makes it difficult for the heart to pump sufficient blood around the body, leading to multiple organ failure. The research will be led at at QMUL's Centre for Trauma Sciences by Chris Thiemermann, Multiple organ failure affects one in three severely injured patients, and one in four of those will die. Those that survive still experience prolonged periods in intensive care, infections and other complications. The trials show that a drug that is proven to be extremely safe, having already been tested in over 180 clinical trials, which is also cheap could be a highly effective option for the NHS and the rest of the world.

The study, published in Annals of Surgery, showed that when injured rats were administered Artesunate, the drug had a marked protective impact on organ integrity and reduced organ failure. The drug appeared to work by enhancing the protection of organs by reducing the body's excessive inflammatory response to injury and blood loss, and by activating well-known cell-survival pathways. On the basis of laboratory tests a new clinical trial is being set up at the Royal London Hospital, UK. Running for two years, Artesunate will be administered to a sample of patients admitted to the Major Trauma Centre, and outcomes measured during their hospital stay and following discharge. This Health Innovation Challenge Fund trial is supported by the Wellcome Trust and the Department of Health.

For more information please see the research paper: 'Artesunate Protects against the Organ Injury and Dysfunction Induced by Severe Hemorrhage and Resuscitation'.

New role of environment in multiple sclerosis revealed by east London study

Environmental factors may be playing a much greater role in the onset of multiple sclerosis (MS) than previously realised, according to early research led by Dr Klaus Schmierer at QMUL and Barts Health NHS Trust. The theory is based on new findings showing that Black people and South Asians in east London have a higher prevalence of MS compared to those groups in their ancestral countries, indicating a strong environmental influence on the disease that could be driving higher MS rates in London.

Studies suggest that ethnicity may be a risk factor, with incidence and prevalence rates generally higher in White populations than in other ethnic groups. Environmental factors appear to include viral infections and vitamin D deficiency.

The study, published by SAGE in Multiple Sclerosis Journal, used electronic records from general practices (GPs) in four east London boroughs (Tower Hamlets, Newham, Hackney and City of London) which were queried for the number of MSdiagnosed patients, grouped by ethnicity. Of 907,151 patients registered with GPs in east London, 776 had a diagnosis of MS. The overall prevalence of MS in east London was 111 per 100,000 (152 for women and 70 for men). The prevalence per 100,000 was 180 for the White population, 74 for Black people and 29 for South Asians. MS appeared to be several times more prevalent among Black people and South Asians living in London compared to those groups living in their ancestral territory. Even the highest prevalence reported for any sub-Saharan African country, 0.24/100,000 in Ghana, is a small fraction of the prevalence of MS in Black people in east London (74/100,000). MS prevalence for people living in India (7/100,000) or Pakistan (5/100,000) was

also much lower than for South Asians living in east London (29/100,000). The findings only apply to east London, and must be interpreted with caution if generalised to the rest of the UK. Due to the possibility of some people with MS being missed in GP datasets, the researchers say they are likely to have underestimated prevalence estimates by approximately a quarter, but that there is little risk for biases in data by ethnicity.

For more information please see the research paper: 'Ethnicity and prevalence of multiple sclerosis in east London'

QMUL Professor wins £245k innovation prize

Prof Kevin Homewood, of the School of Physics and Astronomy, has won a £245k Brian Mercer Award for Innovation to further his research into silicon detectors.

The prize, awarded by the Royal Society, will help Prof Homewood develop new technology that will enable silicon-based photodetectors to detect wavelengths of light which previously could only be detected by devices using highly toxic materials. The future application of silicon photo detectors working at these wavelengths includes use in smart buildings and cities; reducing energy consumption, greenhouse emissions and pollution. It also widens the use of silicon photonics technology in areas such as human health, for example diagnostic breath testing. They could also be integrated with other silicon microelectronics which underpin information technology and the digital world as we currently know it.

The Brian Mercer Award for Innovation is for scientists who wish to develop an already proven concept or prototype into a near-market product ready for commercial exploitation. The award is designed to promote innovation and fill the funding gap between scientific research and the exploitation of an idea through venture capital investment. For further information please see the QMUL website.

Events

Research Matters: changing lives in east London and beyond

As covered above, Barts Health and QMUL are hosting an afternoon of talks from leading academics, clinicians, patients and others, presenting the very best examples of local healthcare research and development. The event will take place **Tuesday 24 May, 4.30-6pm.**

Come along and find out about some of the latest developments in research at Barts Health and Barts and the London Medical School. There will be a reception following the presentations, providing an opportunity to network and ask our speakers any questions you may have. To found about more and to reserve your place please click here.

RDS London drop-in clinics

RDS London holds regular next drop-in clinics for researchers preparing applications to NIHR Applied Health Streams (RfPB, EME, HTA, Programme Grants, Programme Development Grants and Fellowships) or medical charities. Drop-ins take place in East London on the last Friday of the month. RDS London can support researchers at all stages of preparing grant applications. Advice and guidance can be provided on study design, identifying a research team and targeting an appropriate funding stream.

The next East London clinics will be held on Wednesdays: 27 April, 25 May and 29 June. All at 1-3pm.

There is no need to book, just turn up on the day: Room G15, Yvonne Carter Building, 58 Turner Street, London, E1 2AD (reception: 020 7882 5882). For more information please click here.

Nice Forum 2016

On the 6 July in Manchester the NICE Forum 2016 will bring together providers,

policy and industry to learn about and share the latest in evidence-based guidance and joint working.

Offering fundamental support to the work you do, the NICE Forum 2016 will showcase practical examples of how you can work with NICE. As well as best practice case studies and the latest on NICE guidance and standards, the Forum will provide you with an opportunity to learn more first-hand from the leaders at the forefront of the healthcare landscape.

Two main streams will run through this year's forum:

- Using NICE guidance to provide affordable, safe, effective care; and
- Accelerating the adoption of innovation in the NHS

Click here to learn more about the work of NICE and to book your place at the NICE forum 2016.

National Science and Innovation Conference

This year's conference will take place on Tuesday 14 June at The QEII Centre, Westminster.

Science and innovation makes a vital contribution to UK growth. It is at the forefront of the government's commitment to promote growth and economic development, with a number of initiatives to transform the research structuring bodies and utilise investment in science.

The 2016 Science & Innovation Conference will explore the proposed structural innovative changes to research funding, whilst providing delegates the opportunity to discuss and explore new investment areas and collaborative working between academics and businesses to secure future development.

For further information and to register your place, click here.

Training

JRMO Monitoring Workshop

The JRMO will host its second Monitoring Workshop on Thursday 21 April 2016, 3-5pm in Whitechapel. The aim of the workshop is to provide an open forum for colleagues to meet with colleagues who they may otherwise not routinely work with.

This workshop will focus on Inclusion and Exclusion criteria SDV, identifying serious breaches and dealing with sites that do not action findings. This will be of interest as it is based on feedback from the last workshop. At this session we will also discuss the remit of future workshops, and we will be seeking input regarding how the sessions take place – such as format, session length, topics covered and location.

The workshop is primarily aimed at Clinical Trial Monitors, but others who work with the Monitors such as Clinical Trial Facilitators, Clinical Trial Managers, Trial Coordinators and QA Managers may find it helpful as an opportunity to discuss, share and explore best practice and barriers relating to clinical trial monitoring.

Please email Research.Monitoring@bartshealth.nhs.uk to register for the workshop.

JRMO GCP training

To book your place on JRMO run GCPrelated training courses please visit our website.

The core courses available remain:

- Introduction to good clinical practice (GCP) - a full day course for people undertaking clinical trials involving medicinal products only.
- Research governance framework (RGF) - a half-day course for people undertaking non medicinal products research.

For more information on dates and instructions on how to book your places please see the JRMO website.

Please be advised that any GCP and RGF courses run at JRMO queries can be forwarded to research.training@bartshealth.nhs.uk.

Clinfield training

Clinical Research runs a number of courses aimed at those new to the field of clinical research as well as those who have gained experience in the field but who would like to refresh their knowledge and skills and pick up tips and tools to enhance their practice. Over the next few months the following training is being offered (click to see more):

- Developing yourself in clinical research - April 13, London
- Lab skills for clinical research staff -April 25, London
- Clinical research: getting started -April 27, London
- Informed consent May 11, London
- Applying for ethical approval in the NHS - May 25, London
- Meeting the challenges of recruitment and retention in clinical research -June 15, London
- Lab skills for clinical research staff -June 24, London

A Practical Guide to Cluster Randomised Trials

Barts Pragmatic Clinical Trials Unit is running a course based on the book 'A Practical Guide to Cluster Randomised Trials in Health Services Research' by Sandra Eldridge and Sally Kerry. The course is split into three categories and attendees can opt to attend the full, introductory or advanced course. The introductory course covers ethics, recruitment, piloting, design, reporting, principles of health economics, monitoring and process evaluations with introductions to analysis and sample size calculations. The advanced course covers systematic reviews, health economic analysis and statistical aspects such as design, analysis and sample size calculations in more

detail. Places are strictly limited to 25. Early booking is recommended.

The course will run Monday-Friday, 13-17 June 2016. For further information and to book a place please click here.

Research funding

NIHR funding deadlines

Programme Grants for Applied Research - Invitation for Applications

Closing date: 27 July 2016

The NIHR Programme Grants for Applied Research programme invites Stage 1 research proposals to develop individual programmes. Research funded through a Programme Grant typically consists of an interrelated group of high quality projects focused on a coherent theme and hence require multidisciplinary approaches, including clinical, health economics, statistics, qualitative and behavioural sciences, to ensure that research objectives can be met. The amount awarded and the length of the funding period will depend on the nature of the proposed work, in particular whether or not the proposal includes a substantial powered trial. For more details on how to apply, click here.

Health Technology Assessment Programme - Researcher-led call

Closing date: 14 April 2016
The Health Technology Assessment
Programme is accepting calls to their
researcher-led workstream. The deadline
for applications is 1pm, 14 April 2016.
Highlight notice: organisation and quality
of end of life care services. For the current
funding round we welcome proposals
around the organisation and quality of care
in the last year of life. This includes
research to identify cost-effective models
of specialist palliative care and evaluation
of other promising service innovations to
provide joined-up, person-centred care to
those at the end of life.

Public Health Research Programme - Commissioned call

Closing date: 26 April 2016

The Public Health Research Programme is accepting applications to their commissioned workstream for the following topics:

15/189 – Interventions to build resilience in children and young people

15/193 - Preventing uptake of smoking by children and young people For more information and to apply, please click here.

Public Health Research Programme - Commissioned call

Closing date: **26 April 2016**The Public Health Research Programme is accepting applications to their commissioned workstream as follows: 15/129 Local interventions to reduce intake and harm from alcohol For more information and to apply please click here.

Programme Development Grants

Submission deadline: 22 July 2016 Programme Development Grants are designed to increase the rate and number of successful applications for a full Programme Grant. They are a response to an observation that some otherwise very promising applications had been unsuccessful because parts of the proposed programme were considered to be too insecure and hence would be too risky for a substantial programme grant. Programme Development Grants provide a mechanism to address and rectify such weaknesses by supporting the completion of the necessary preparatory work to suitably position the research team to submit a competitive Stage 2 Programme Grant application. For more information and to apply please click here.

For more information about all NIHR funding opportunities visit the NIHR website. To subscribe to the NIHR's themed call mailing list please click here.

HEE/NIHR Integrated Clinical Academic Programme - Round 2 Competitions

The Health Education England (HEE) and National Institute for Health Research (NIHR) Integrated Clinical Academic (ICA) Programme provides personal research

training awards for healthcare professionals (excluding doctors and dentists) who wish to develop careers that combine clinical research and research leadership with continued clinical practice and clinical development.

- Clinical Doctoral Research
 Fellowships: Enables graduate
 clinicians with some research
 experience and aspirations for a
 clinical academic career to obtain a
 PhD whilst developing their clinical
 skills. Closing date: 19 May 2016
- Clinical Lectureships: Enables early post-doctoral clinicians to combine independent research in an academic position with continued clinical practice and professional development.
 Closing date: 28 April 2016
- Senior Clinical Lectureships:
 Enables practicing clinicians with independent clinical research experience to undertake further research in a senior academic position whilst developing as a clinical academic leader. Closing date: 28 April 2016

For further information and to apply visit the NIHR website here.

Bill & Melinda Gates Foundation and partners: Grand Challenges

Bill & Melinda Gates Foundation and its funding partners in the Grand Challenges family of grant programs are inviting innovators to apply for three grant opportunities:

Grand Challenges Explorations fosters early-stage discovery research to expand the pipeline of ideas for solving our greatest global health and development challenges. Launched in 2008 with an initial \$100 million commitment from the foundation, Grand Challenges
Explorations grants have already been

awarded to more than 1100 researchers from more than 60 countries.

Applications are open on the following six topics until **May 11, 2016**:

- Assess Family Planning Needs, Preferences and Behaviours to Inform Innovations in Contraceptive Technologies and Services
- Develop Novel Platforms to Accelerate Contraceptive Drug Discovery
- Design New Analytics Approaches for Malaria Elimination
- Accelerate Development of New Therapies for Childhood Cryptosporidium Infection
- Novel Approaches to Characterizing and Tracking the Global Burden of Antimicrobial Resistance
- Explore New Solutions in Global Health Priority Areas

Initial grants will be US \$100,000 each, and projects showing promise will have the opportunity to receive additional funding of up to US \$1 million.

The Blue Economy Challenge: Launching a Blue Revolution for Aquaculture

This challenge aims to find solutions to three important issues of aquaculture: Rethinking feed for aquaculture; new ocean products; and sustainable design by encouraging innovations that will revolutionize aquaculture in the developing world with a focus on the Indian Ocean region, where transformations in aquaculture can help eradicate poverty, end hunger, and preserve ecosystems. The application deadline is **June 30**, **2016**.

For more information please visit the Blue Economy website here.

Research professional:

Research Professional (formerly Research Research) now offer an easy to use self-service sign up: http://www.researchprofessional.com/

Funding information: Further funding information can be found on the Research Professional website – to access click here (account and password required).