Queen Mary University of London

NHS Barts Health NHS Trust

Joint Research Management Office

Research News Bulletin

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Research restart!

With spring research begins anew.

Although some of our laboratory and analysis-based research never stopped last year, most of our non-Covid related clinical research had to stop as staff were re-deployed into more urgent Covid 19 front line duties. Slowly, as this year begins to warm-up researchers and their staff are planning how they can return to delivering safe research for patients across our wide field of specialisms.

In February Prof Rupert Pease, Clinical Director of R&D wrote to our researchers letting them know that that guidance was now available on how clinical research re-start would be prioritised at Barts Health and Queen Mary. He thanked all researchers for their patience through this difficult time of transition, reminding clinical staff who have been redeployed that they made a vital contribution to patient care; only recently we passed 10,000 participants recruited into Covid-19 research studies at Barts Health.

Guidance on undertaking research in what remain difficult times is available on the JRMO website.

Any questions about re-opening particular studies should be directed to the JRMO's Research Governance team at research.governance@qmul.ac.uk

The JRMO's guidance remains consistent with the NIHR Restart Framework. That was developed in partnership with stakeholders and the devolved nations, the Framework provides a flexible structure for local decision-making.

The goal is to restore a fully active portfolio of NIHR research while continuing to support important Covid-19 studies as part of the Government response to the pandemic.

All researchers were able to restart their studies from 22 February, based on agreed criteria. If there was a formal suspension of your study during the first lockdown then a formal restart process will be required. If the studies were simply paused as part of the latest lockdown then no formal restart process is required.

JRMO processes for study set-up will be slower than usual and prioritisation by study type will be implemented to establish which studies get set up first. You can find this priority listing on the JRMO website.

Bulletin contents

Updates and guidance for our researchers on matters relating to research and the Covid -19 virus can be found on the JRMO website

VIP visit to Barts Health Vaccines Trials Centre

Staff at the Barts Health Vaccines Trials Centre received a visit in mid-March from Group Chief Executive, Alwen Williams and Professor Sir Mark Caulfield, Chair of the Barts Health / Queen Mary Covid-19 Research Delivery and Operations Group. Together with Gerry Leonard, Director for Research Development, they came to view the trials centre and meet and thank the team for their efforts in setting up and successfully delivering the Trust's first Covid-19 vaccine trial.

The trials centre is situated in the historic Bethnal Green Library, based in the heart of the east-end London community. The grade II listed building closed its doors to the public at the start of the pandemic and remained closed until the Barts Health research delivery group recognised its potential as a trials site.

In September 2020, having worked closely with local authority partners, Barts Health entered the building and began work to convert it into a bespoke vaccine trials centre. The centre had to meet the rigorous standards required by regulatory bodies such as the Medicines and Healthcare Products Regulatory Authority (MHRA) and Health Research Authority (HRA) and have the capacity to handle up to 40 participants every day, in a Covid-19 safe way.

Alwen, Mark and Gerry were shown around the centre by members of the research team, including Claudio Melchiorri, GCS Research Operations Manager and Professor Patrick Kennedy, Principal Investigator for the ENSEMBLE 2 trial.

During their visit, they met and spoke with some of the research nurses, medical students and volunteers who have contributed to the successful delivery of this trial. Now closed to recruitment and awaiting results, 682 participants were recruited to the ENSEMBLE 2 trial at the Bethnal Green Library, making Barts Health the top recruiting site in the UK.

The team had a chance to share some of their experiences over the past few months, including some of the positive feedback they've received from local residents who took part in the trial. Even though recruitment to the trial has closed, the team are still working at the library.

For information about Covid-19 research, please visit the JRMO or Barts Health websites.

Barts Health Patient and Public Involvement in Research (PPIR) working group – new members wanted!

The Research Engagement and Diffusion team run a Patient and Public Involvement in Research working group which provides a forum for staff who are interested in patient and public involvement and engagement (PPIE) in research. The group aims to improve standards in PPIE in research practice and to build stronger connections with our diverse local population. The team is seeking new members to join the group, so for more information, please contact Patientsinresearch.bartshealth@nhs.net

Key changes to UK amendment process

The HRA and the MHRA have agreed to make two key changes to the UK amendment process with effect from 25 March 2021.

Firstly, the addition of a new NHS/HSC site or a change of PI at an NHS/HSC site for a CTIMP study will now be classified as a Non-Substantial Amendment. This was previously considered a Substantial Amendment. The change is designed to speed up new site set up. This is possible because new sites were categorised as substantial due to EU guidance and therefore, from January 2021, we can take a different interpretation for NHS/HSC sites due to the UK system in place. The amendment tool will provide the appropriate categorisation and guidance on the next steps to take. The Standard Operating Procedures for Research Ethics Committees have also been updated to reflect this change. There is no change to the classification of amendments

relating to new sites/change of PI at **non**-NHS sites in CTIMP studies.

Secondly, the amendment tool can now be used to notify MHRA of substantial amendments in place of the Annex 2. This should save applicant's time by reducing the number of forms to be completed. The Annex 2 may still be used to notify the MHRA of 'bulk' amendments (identical changes to multiple studies at one time) and will be available on the MHRA website.

The amendment tool is being updated and a new version will be available shortly. Video training will be available from the HRA's Learning Management System. If you have any further questions, contact amendments@hra.nhs.uk for support.

You can provide feedback on the amendment tool using our online survey.

Covid-19 vaccine research: a community conversation

The Research Engagement and Diffusion hosted a community conversation about Covid-19 vaccine research back in December.

Chaired by Abbas Mirza, Community Engagement Lead, Barts Health, the event saw over 150 guests login to hear from Dr Vanessa Apea about the impact of Covid-19 on ethnic minority and Professor Patrick Kennedy about taking part in the Janssen ENSEMBLE 2 vaccine trial at the Barts Health Vaccine Trial Centre in Bethnal Green Library. Yunus Dudhwala led a short panel discussion with community leaders and members of the public about Covid-19 vaccine research.

Find out about future events by checking the Barts Health 'Take part in research' site.

Inclusion, equality and diversity in healthcare research

Not only is there growing evidence that ethnic minority communities feature disproportionately in the numbers of those acquiring Covid-19, and in consequential fatalities, but it is also the case that these communities are often under-represented in health and social care research and clinical trials, in particular.

The Centre for BME Health has compiled a toolkit, and checklist, to give researchers a framework of best practice to improve participation of diverse communities in their research.

Points to consider

- Being more equality-focused in your research ensures that you are meeting the stipulations of the Equality Act 2010. In particular, your research should focus on engaging with people from the nine **protected characteristic** backgrounds, one of which is race.
- Being equality-minded means you are less likely to discriminate, however unintentionally. It also means treating people differently and flexibly to ensure equality of opportunity. In other words, **one size doesn't fit all**.
- Recognise that there is a **need** to engage. And then focus on **why** that is the case.

For more information, visit the Centre for BME health website and the NIHR blog 'ensuring ethnic diversity in-Covid-19 research'

Public involvement in a pandemic

The HRA has launched Public Involvement in a Pandemic, its report into the work of the UK Covid-19 public involvement matching service. Set up to tackle the drop off in public involvement in urgent public health studies set up quickly at the start of the pandemic, the matching service, an HRA collaboration with partner organisations from the NHS, university, and charity sectors, allowed researchers to access public involvement support if they did not have existing suitable public involvement connections.

Six months on, the low level of public involvement in Covid-19 research recovered to – and exceeded – the normal level of public involvement in all approval applications. We are exceptionally proud of this work.

If you missed our launch event you can watch it online on the HRA's YouTube channel. If you'd like to hear more about how this work develops in the future, email public.involvement@hra.nhs.uk.

HRA eligibility criteria for student research (effective from 1 September)

The HRA has now reviewed its approach to study approval for student research.

That review aimed to ensure students have the best learning experience of health and social care research, whilst also reducing the time that the HRA, DAs and NHS Research Ethics Committees (RECs) spend advising on and reviewing student applications.

In March 2020 the HRA paused student research approvals to create capacity for urgent Covid-19 research. Now, from 1 September 2021, it is introducing new eligibility criteria for standalone student research.

The new criteria mean that some Master's level students will be able to apply for ethics review and HRA/HCRW Approval. Stand-alone research at undergraduate level, that requires ethics review and/or HRA/HCRW Approval, cannot now take place. Arrangements for doctoral research remain unchanged. Full details of this are in table one - permitted student research table. The HRA has also made it clear when students are able to take on the role of Chief Investigator, see table two - which type of students may act as Chief Investigator?.

The HRA has decided that it is possible for students to learn about health and social care research without completing stand-alone projects. It is important, it says, to look at other ways to build skills and experiences that can better reflect modern research and emphasises team science. View the video of the HRA site 'Exploring good practice in Student Research' to hear from course leaders about how successful alternative approaches have been or visit the HRA website to read more.

If you have any questions about eligibility criteria, please contact queries@hra.nhs.uk.

Covid-19 research at Barts Health/ Queen Mary

The JRMO's expedited review Covid-19 Committee continues to meet weekly to review new C-19 project proposals. Information about the committee, including its terms of reference, is available on the JRMO website.

Proposals for new projects must be submitted to the JRMO research governance team - research.governance@qmul.ac.uk - by 4 pm the Friday before they will be reviewed.

Since the start of the pandemic the review committee has met 48 times & reviewed a total of 434 projects: 222 Research projects (JRMO Governance); 112 Trust Clinical Effectiveness Unit service improvements/audits/service evaluations; and 100 Queen Mary Ethics of Research Committee (QMERC) projects (non-NHS projects). **11,816** participants have been recruited into Covid-19 studies as of mid-March.

EU funding available

Under the post-Brexit UK/EU trade deal, the UK will 'associate' to the EU research programme 'Horizon Europe' (2021-2027) on equivalent terms to EU member states. The UK and EU need to formally adopt the association agreement still the European Commission's Q&A document confirms UK entities are already eligible to apply for Horizon Europe calls. UK researchers will be able to be a partner and lead Horizon Europe projects from the start and be eligible for funding from the collaborative research schemes and 'bottom up' research schemes such as the European Research Council and Marie Skłodowska-Curie Actions. The European Research Council (2021) work programme is the first to be approved and calls launched. The UK is eligible for these first ERC deadlines: Starting Grants is 8 April 2021 and Consolidator Grants is 20 April 2021.

As per the Withdrawal Agreement, UK participation in EU programmes under the period 2014-2020 remain unchanged. Successful UK participants will still be awarded 'Horizon 2020' funding and be paid by the EC for the project's full duration.

Keep up to date on Horizon Europe via the JRMO EU Unit Portal for funding opportunities, bespoke guidance, news and webinars or discuss with the EU Unit team.

Leaving the EU guidance

The MHRA has published guidance for researchers on some of the practical impacts of 'Brexit' on their work. Summarised below are some headline messages for the academic research community. Please also visit GOV.UK transition for more comprehensive guidance.

Personal Data

The European Commission published its draft UK adequacy decisions on 19 February. If adopted these will allow for the continued free flow of personal data from the EU and EEA to the UK. Further information is available on the Information Commissioner's website.

Personal Data can easily flow from the UK to the EU/EEA and any transfer of personal data from the UK to another country is an international transfer. The ICO provides help with international transfers. If there is no adequacy decision for the country (to which the UK is transferring Personal Data) then the transfer is a so-called 'restricted transfer' (generally managed using SCCs). In terms of transparency, the ICO advises that transfers of Personal Data to third countries or international organisations should be included in transparency information.

Border changes

Customs procedures and physical checks at borders are changing. The UK is taking a phased approach to these changes (stage 1 changes were implemented on 1 January 2021, and the final stage 3 changes will apply from July 2021). The Border Operating Model provides further detail about each stage and the types of 'goods' to which each stage applies. This has implications for the import and export of clinical research supplies and samples (including medicines, devices, consumables and biological samples) from/to the EU and for moving goods to or from Northern Ireland. If this is relevant to you, then you may find the following questions and links helpful:

- Is anyone in your organisation knowledgeable in customs and export? Can you tap into existing expertise and/or processes?
- Will your organisation handle new Customs and Safety and Security Declarations in-house or will someone deal with customs for you?
- Check whether your organisation has an EORI number?
- importing goods from the EU
- exporting goods to the EU
- moving goods to or from Northern Ireland
- imports and exports: general enquiries

If you supply medicines or medicinal products then you can register for the express freight service. This service is available to suppliers in any UK country. For any issues please email: ctcontingencyplanning@dhsc.gov.uk.

The above information is UK-specific. Imports and exports to or from the EU also have customs procedures and physical checks in the relevant EU member state. Learn more about the EU ICS2, launching 15 March 2021 and the national requirements of the EU member states.

Transfer of human tissue

If you import or export human tissue or tissues and cells from/to the EU, then the information on border changes above is relevant to you, and you may find UK GOV's guidance on import duty and VAT for research useful. If you work in the human application sector, for example, cell or tissue therapies, you may also need to make changes to your HTA licence. You have 6-months (from 1 January 2021) to make any changes. There are no changes to the HTA licensing requirements for the research sector.

Drug Trials (CTIMPs)

New guidance and information for industry from the MHRA is the headline page for accessing their post-transition guidance (relevant for academia):

- You will still need a EudraCT number, at least in the short term.
- Your Clinical Trial Application form for the MHRA should be completed in IRAS.
- Sponsors should use MHRA's IT systems to make clinical trial submissions (i.e. initial applications, substantial amendments, End of Trial notifications and Developmental Safety Update Reports (DSURs)).

You may find the following links helpful:

- Guidance on submitting clinical trial safety reports (includes some guidance on dual reporting if your trial is on-going in the UK and European member states).
- Registration of clinical trials for investigational medicinal products and publication of summary results
- Guidance on substantial amendments to a clinical trial

HRA guidance for sponsors is now also available.

Medical Devices

Your Clinical investigations of medical devices should be submitted via IRAS. EU Medical Devices Regulation (EU MDR) and EU in vitro Diagnostic Regulation (EU IVDR) will apply in Northern Ireland from 26 May 2021 and 26 May 2022 respectively. Whilst EU MDR and EU IVDR will not apply in England, Wales and Scotland (GB); you may wish to comply with these regulations to market in both the EU and UK. EU Notified Bodies and CE marking will be recognised by MHRA until 30 June 2023.

Oxford Global Guidance – Helps you navigate the EU MDR and EU IVDR and classify your device. The European Commission also has factsheets to help with compliance. You may find the following links helpful:

- Regulating medical devices in the UK
- Guidance for retailers: supplying medical devices to Northern Ireland
- Register medical devices to place on the market
- Medical devices: conformity assessment and the UKCA mark

If you have a specific question about leaving the EU and the implications for health research, you can contact the MRC at rsc@mrc.ukri.org.

New HRA guidance regarding GP indemnity for research

The HRA website contains guidance on setting up and delivering a study in primary care settings. On behalf of the CRN, Phil Evans (NSL for Primary Care and Cluster C Co-Lead) has worked with HRA, and in collaboration with NHS Resolution, to develop a set of frequently asked questions relating to the state-backed indemnity scheme for general practices in England (CNSGP) and how this provides cover for the conduct of research in general practice in the NHS.

JRMO Procurement page updated

All purchasing of equipment and consumables for research projects need to be made in line with the procurement regulations of the relevant sponsoring organisation, Barts Health or Queen Mary, as appropriate. Full information on arrangements for both

organisations can be found on the JRMO website.

You are strongly advised to review the relevant processes for procurement and to speak to a member of the relevant procurement team, or your account manager within the JRMO, before making any commitments. You should also ensure that there are sufficient funds in the relevant research account to cover the cost of the proposed purchase.

Changes to Queen Mary Ethics of Research review application process

Improvements in the Queen Mary Ethics of Research review application process have led to changes in the information available to researchers. Staff and students are now requested to complete a revised QMERC Research Ethics Application form and use the new user-friendly Participant Information Sheet and Consent Form templates and guidance.

Reesearchers should familiarise themselves with the content of the QMERC webpage which contains current application forms, guidance, training tools, the requirements for international research, the exemptions from QMERC ethical approval, closing dates for submissions and current Covid-19 guidance. Please update your policies and procedures as applicable. The team are available for advice and support by contacting research-ethics@qmul.ac.uk.

JRMO SOPS and Guidance changes

Since December the following Standard Operating Procedures (SOPs) and supporting documents have been released:

SOP 16b External Access to Patient Electronic Health Records
- TAC Guardian Authorisation Form
- TAC Audit Log Form
- TAC Usage Log Form
- 3rd party Confidentiality Statement for Barts Health

SOP 24 Quality Management System
- JRMO Quality Objectives

The following associated documents have also been released, although the related SOPs are still under review:

SOP 11a Sponsorship of MHRA regulated studies (For researchers)
- JRMO Protocol Template for MHRA regulated studies
- JRMO document submission checklist

SOP 11b Sponsorship of MHRA regulated studies (For the JRMO)
- Guidance for GCP and Governance section staff
- Early engagement meeting tool
- Governance team sponsorship review
- GCP Managers set-up checklist
- Sponsor CI agreement (Barts Health)
- Sponsor CI agreement (Queen Mary)

SOPs 12a Barts Health/ Queen Mary Sponsorship of interventional studies (Researchers)
- JRMO protocol template for interventional studies
- JRMO Interventional Studies Document Submission checklist
- Barts Health NHS Trust Sponsor-CI Agreement for Interventional Studies
- Queen Mary Sponsor-CI agreement (CI) for Interventional Studies
- Declarations of no cost (New Studies)

SOP 12b Barts Health/ Queen Mary Sponsorship of interventional studies (JRMO)
- JRMO Governance Team Sponsorship Review for interventional studies
- JRMO Sponsorship review proportionality document
- Early engagement meeting
- Clinicaltrials.gov guidance document
- Sponsorship with conditions email template
- Queen Mary Sponsorship (with conditions) letter (Interventional and Research)
- Barts Health Sponsorship (with conditions) letter (Interventional and research studies)
- Confirmation of sponsorship email

SOP 13a Barts Health/ Queen Mary Sponsorship of research studies (Researchers)
- Study Approvals Reference Table
- JRMO protocol template for research studies

- JRMO protocol template for Research Tissue Banks and Research Databases
- JRMO Research Studies Document Submission checklist
- Barts Health NHS Trust Sponsor-CI Agreement (CI) for research studies
- Queen Mary Sponsor-CI agreement (CI) for research studies

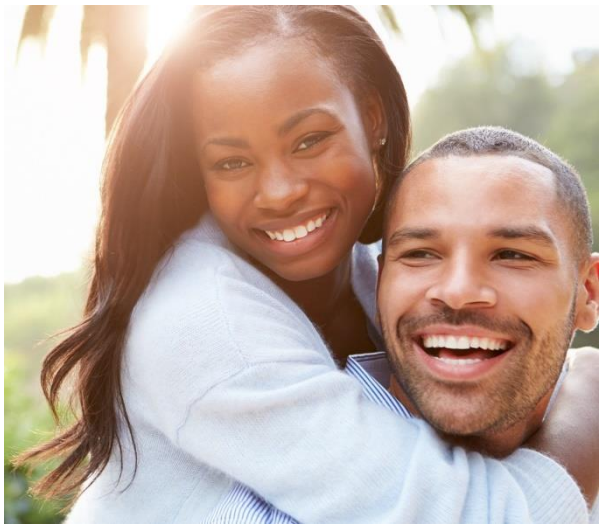
SOP 13b - Barts Health/ Queen Mary Sponsorship of research studies (JRMO)

- JRMO Governance Team Sponsorship Review for research studies
- Retrospective Data studies guidance document
- Sponsorship and capacity and capability for retrospective anonymised data studies email template

All JRMO SOPS can be found on the JRMO website, in the SOP section.

Our research

Train yourself to become more optimistic!



An article in Harper's Bazaar has featured research from Queen Mary looking into how we might train ourselves to become more optimistic.

The definition of optimism is hopefulness, confidence about the future or success of something. Optimists see their glass as half full, not half empty, but are we wired one way or the other and is it possible to train ourselves to become more optimistic?

Research from Queen Mary University of London in 2020 on 2,800 identical and non-identical twins established sensitivity levels to positive or negative experiences were roughly half and half, 50% genetic and 50% environmental. It is possible to rewire negative thought circuits; this, after all, is the basis of Positive Psychology, a field of study that supports individuals to build lives of meaning and purpose. Shadow skulkers can learn to move towards the light.

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According to Carolyn Mair PhD and behavioural psychologist, cultivating a more cheerful disposition has many advantages including “longer life, more successful relationships and better physical health”. She explains that “stress manifests itself as a hormone in the body which in the short term is fine but over a long period can damage the heart and other organs.” Perpetual negativity can also impair self-esteem and mar relationships with others.

So how can ruminators become radiators? Psychologist Mihaly Csikszentmihalyi believed that “happiness doesn’t just happen but must be prepared for and cultivated”. 8 ways to a more optimistic outlook were suggested:

1. Create a repertoire of positive memories
2. Start a ‘gratitude diary’
3. Imagine your best future self
4. Cut loose the negativity
5. Protect yourself from ‘energy vampires’
6. Do something for someone else
7. Walk, enjoy nature, hug a tree!
8. Go with the flow

You can read the full Queen Mary story here.

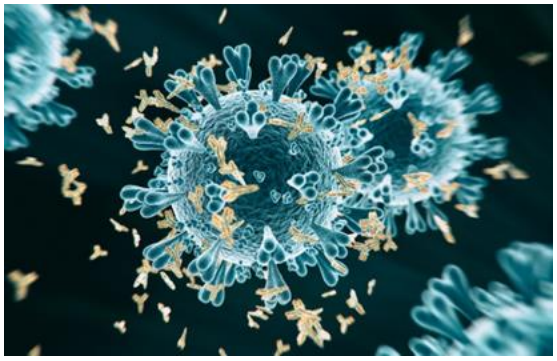
Study finds evidence of lasting immunity after mild or asymptomatic Covid-19 infection

New research involving scientists from Queen Mary University of London has found evidence of protective immunity in people up to four months after mild or asymptomatic Covid-19.

The study, published today in Science Immunology, analysed antibody and T cell responses in 136 London healthcare workers who had mild or asymptomatic Covid-19 infection dating back to March 2020.

The team, including researchers from Queen Mary, Imperial College London and University College London, found that 89% of healthcare workers analysed carried neutralising antibodies 16-18 weeks after infection.

From the outset of the pandemic, scientists across the globe have been working to understand how our immune system protects us against SARS-CoV-2, and how long this protection lasts.



Much of this debate around protective immunity has focussed on the different roles of B cells, which make antibodies, and T cells, white blood cells which work in several different ways to help protect from viruses, including direct killing.

In this study, the researchers show that whilst protective antibody responses were usually complemented by a T cell response, over half of the healthcare workers had mismatched antibody and T cell responses, and did not produce a T cell response specific to proteins found on the outer layer of the SARS-CoV-2 virus. They also found that T cell responses tended to be higher in those with the classic, defining symptoms of Covid-19, while asymptomatic infection resulted in a weaker T cell immunity than symptomatic infection, but equivalent neutralizing antibody responses.

The researchers found most also had T cells capable of recognising multiple different parts of the virus, however, the two responses did not always persist in harmony, with some individuals showing T cell immunity but no evidence of antibodies, and vice versa.

You can read the full article on the Queen Mary website.

Patent for biomarkers for Rheumatoid Arthritis precision medicine filed

QMI has filed a patent on a technology developed by Prof Costantinos Pitzalis and Dr Myles Lewis. The method enables the stratification of patients for treatment with tocilizumab versus rituximab by integrating molecular pathology into the treatment decision-making in Rheumatoid Arthritis.

Prof Costantino Pitzalis has also been awarded the MRC Industry Collaboration Agreement (MICA): Development and Validation of a Transcriptomic-Based Model for Classifying and Predicting Treatment Response in Rheumatoid Arthritis. The award totals over £600k and will fund collaborative work done with two commercial parties.

Prof Pitzalis, from the Centre for Experimental Medicine and Rheumatology at Queen Mary's William Harvey Research Institute, led the clinical trial, which recruited 164 patients from sites across the UK, Belgium, Italy, Portugal, and Spain. Patients underwent a synovial biopsy and were randomised to receive either rituximab or tocilizumab. Because more than 50% of patients with rheumatoid arthritis have low or absent CD20 B cells - the target for rituximab - in the joint synovium, it was hypothesised that, in these patients, the IL-6 receptor inhibitor tocilizumab would be more effective. When the synovial biopsies were classified in B cell poor/rich using RNA sequencing, the results demonstrated significance in favour of tocilizumab. Although it is too early to make recommendations in clinical practice, the results of this study pave the way for further research to improve patient classification accuracy according to the molecular pathology of the disease tissue to guide optimal treatment allocation in RA patients.

The full results of the study can be found in the Lancet and a Q&A with Professor Pitzalis about the trial can be found on the Queen Mary website.

New class of drug Leads to 30% reduction in cancer deaths

A new type of drug that helps target chemotherapy directly to cancer cells has been found to increase significantly the survival of patients with the most common

form of bladder cancer, according to results from a phase III clinical trial led in the UK by Queen Mary and Barts Health.

The results are published in the *New England Journal of Medicine* and were presented at the 2021 American Society of Clinical Oncology's Genitourinary Cancers Symposium.

Urothelial cancer is the most common type of bladder cancer (90% of cases) and can also be found in the renal pelvis (where urine collects inside the kidney), ureter (the tube that connects the kidneys to the bladder) and urethra. Globally, approximately 549,000 new cases of bladder cancer and 200,000 deaths are reported annually. One of the most widely used treatments for this type of cancer is chemotherapy which works by targeting all the cells in the body, successfully acting upon cancer cells, but also affecting non-cancer cells, causing side effects.

A new class of drugs known as 'antibody-drug conjugates' (ADC) work by having an antibody attached to a chemotherapy-like drug. The antibody specifically targets and attaches to the cancer cells, bringing with it the chemotherapy-like drug, allowing it to only act upon those cancer cells and ignore normal cells in the body.

Lead UK researcher, Tom Powles, Professor of Genitourinary Oncology at Barts Cancer Institute and Director of Barts Cancer Centre said that "This new type of drug has led to a survival advantage in bladder cancer which has been difficult to achieve in this difficult disease. It reduced the death rate by 30 per cent and beat chemotherapy in every setting, so this really is a big deal."

The trial involved 608 patients in 19 countries and tested a new ADC drug, enfortumab vedotin, developed by Astellas Pharma Inc. and Seagen Inc., in adult patients with locally advanced or metastatic urothelial cancer who were previously treated with platinum-based chemotherapy and an immunotherapy drug called a PD-1/L1 inhibitor. It found that:

- The risk of death was 30 per cent lower with the new drug than with chemotherapy, with a median survival of approximately 13 months for the new drug.
- Median progression-free survival, which is the time without progression of cancer, was 5.6 months for the new drug vs. 3.7 months for chemotherapy
- Overall response rate, the percentage of patients with either complete or partial response, was 40.6% against 17.9% of patients in the chemotherapy arm
- The side effects of the drug were manageable and overall similar to chemotherapy.

More information can be found on the Queen Mary website.

Single dose of vaccine acts as 'booster' in those with prior Covid-19 infection

People who have previously had Covid-19 have an enhanced antibody response with a single dose of RNA vaccine, according to a study of 51 UK healthcare workers, around half of whom had a previous laboratory-confirmed Covid-19 infection.

The study showed that a single dose of Pfizer/BioNTech's RNA vaccine resulted in a significantly enhanced immune response against the virus, compared to a single dose in those without prior infection. The enhanced response was at least an order of magnitude greater than after a conventional two-dose vaccine schedule in a previously uninfected individual.

These findings have the potential to inform future vaccination strategies to include serology testing at the time of the first vaccination to enable the second, booster dose to be prioritised for previously uninfected individuals. They explain that such an approach could accelerate vaccine roll-out by stretching vaccine supplies further.

The research, published today in a letter by The Lancet, is a collaboration between researchers at Public Health England, Barts Health NHS Trust, Royal Free London NHS Foundation Trust, University College London, Queen Mary University of London and Imperial

College London - partners in the 'COVIDsortium'.

Áine McKnight, Professor of Viral Pathology at Queen Mary's Blizard Institute said: "Since the beginning of the first wave of the epidemic, our team has been monitoring immune responses to SARS-CoV-2 natural infection in a cohort of approximately 700 healthcare workers from Bart's, The Royal Free and Nightingale hospitals. The rollout of vaccination in healthcare workers presented a unique opportunity to compare the antibody response in volunteers who had a previous infection compared to those who had not."

The work at the Blizard Institute was supported by Rosetrees Trust, The John Black Charitable Foundation, and Medical College of St Bartholomew's Hospital Trust.

Following a single dose of the Pfizer vaccine, participants produced antibodies against the spike protein. In those without prior infection, levels of spike-protein antibodies were similar to peak levels measured seen in individuals with mild SARS-CoV-2 infection. However, those with prior infection produced high levels of antibodies against the spike protein after a single dose, compared to those without prior infection, indicating a significantly enhanced antibody response. Blood analysis of the 24 showed that antibody response (anti-S response) increased 140-fold on average following a single dose of vaccine, compared to their peak pre-vaccine antibody levels – after their infection but before their first vaccination.

The researchers stress that these findings relate to those with laboratory-confirmed infections only at this stage and do not take into account variables such as the amount of virus (viral load) which caused the initial infection, participants age, detailed health status or the severity of their infection.
The study was also restricted to the Pfizer/BioNTech mRNA vaccine in a small group of healthcare workers with and without lab-confirmed infection. It cannot, at this stage, be applied more generally to other groups – such as older adults, people with underlying health conditions – or to other vaccines.
The authors explain that the findings add to the growing picture of immunological protection against SARS-CoV-2 and could inform other programmes around the world where vaccine supplies may be limited.

Type 2 diabetes is associated with increased risk of Parkinson's

Research from Queen Mary University of London has concluded that there is convincing evidence that type 2 diabetes is associated with an increased risk of Parkinson's disease.

The study found that those with type 2 diabetes had a 21% increased risk of developing Parkinson's. However, because Parkinson's only affects around 1-2% of people over the age of 60, people with type 2 diabetes still have a very small absolute risk of developing Parkinson's.

Previous systematic reviews and meta-analyses have produced conflicting results around the link between diabetes and the risk of Parkinson's disease. This new study, published in the Movement Disorders Journal, used a meta-analysis of observational data and meta-analysis of genetic data to evaluate the effect of type 2 diabetes on the risk and progression of Parkinson's disease.

Corresponding author Dr Alastair Noyce from Queen Mary said that "This research brings together the results from many other studies to provide convincing evidence that type 2 diabetes likely affects not only Parkinson's risk but also Parkinson's progression. There are many treatment strategies for type 2 diabetes, including prevention strategies, which may be re-purposed for the treatment of Parkinson's."
The authors say that the most important implications of those findings are that drugs that are already available for type 2 diabetes might help reduce the risk and slow the progression of Parkinson's. They also say that screening for and early treatment of type 2 diabetes in patients with Parkinson's may be advisable.

The Preventive Neurology Unit is funded by Barts Charity. Funding for co-authors came from the Michael J. Fox Foundation, the

Canadian Consortium on Neurodegeneration in Aging (CCNA), the Canada First Research Excellence Fund (CFREF), Parkinson Canada, and the Intramural Research Program of the NIH, National Institute on Aging.

Training

JRMO research governance training

As a result of the Covid-19 pandemic, JRMO GCP training is currently being delivered online, using a mix of MS Teams tutorial, pre-reading and undertaking the NIHR Introduction to GCP. This approach helps keep the online element shorter and more focussed on Barts Health and Queen Mary requirements, CI responsibilities and JRMO SOPs. Please note that places on these courses are limited to 25 people per session.

Barts Health staff and Queen Mary staff and students should book research governance training using the Queen Mary CPD online booking system, but please note you will need a QMUL email address to do this.

If you are already booked on a course, you will not lose your place if you have an NHS.NET email address. However, if you wish to join a GCP or Governance course or book onto one of these in the future and you do not have a QMUL email account, please email cpd@qmul.ac.uk and the team will manually add you to the course.

JRMO courses are also open to staff working on NIHR portfolio studies across North Thames free of charge and to external participants for a fee. Individuals in either group should contact research.governance@qmul.ac.uk for course details and fee information.

Please note the following:

- New users need to register before booking (select the register button on the site and follow the instructions) with a Queen Mary email address
- All users will be asked to select an appropriate course
- Please ensure that you read the details of each course and meet the description of the target audience;
- Select a date and course to meet your needs
- Once you have made your booking, you will receive an automated email to confirm your place
- We can only accept booking through the above route

More detail on all these courses is available on the 'What training do I need' webpage.

Video resource for research ethics: QMERC review process and reviewer expectations

A video has been developed by the JRMO Research Ethics Office to introduce the Queen Mary Ethics of Research Committee review process to the Institute's staff and student community.

The expectations of Committee members and Research Ethics Facilitators who review ethics applications are also discussed. To that end, advice is provided on how to submit a well completed and well-documented research ethics application.

The video can be accessed online, using your Queen Mary login.

WFC Training

Current restrictions on travel and group meetings makr it difficult to deliver face-to-face training at the moment, but WFC can arrange online training sessions or take face-to-face bookings for later in the year if preferred.

WFC recognises that your needs are unique and an off-the-shelf solution is rarely sufficient. As such, we offer our selection of training, education and workforce development courses on a hosted basis only. Hosted courses are capped at 15 delegates (face-to-face) to ensure that an entire team can attend. Hosted courses are delivered upon the request of a client; the client provides the training venue and the course is scheduled according to their needs. The content of the course is developed to be fully bespoke to the client.

Contact WFC to discuss your bespoke needs for 2020.

Recent courses have included:

- Understanding and applying AcoRD principles (Including a module covering the use of the SoECAT and NHS England ETC process)
- Informed consent for research
- Clinical protocol development
- Principles of clinical research involving human subjects
- Regulatory compliance in clinical research
- Effective sponsorship of research

Research funding

European Research Council first calls under Horizon Europe announced

The European Commission has approved the European Research Council (2021) Work Programme and call deadlines. This is the first work programme and calls under the EU's R&I programme 'Horizon Europe' (2021-27). €1.9bn budget will fund c. 1,000 top talented researchers to pursue frontier research in any discipline - of which 66% is for early to mid-career researchers to lead a team re breakthrough scientific and technological discoveries that can form the basis of new industries, markets, and social innovations of the future.

The first ERC deadlines are:

- Starting Grant: opens 25 February, call deadline 8 April 2021
- Consolidator Grant: opens 11 March, call deadline 20 April 2021
- Advanced Grant: opens 20 May, call deadline 31 August 2021

The first ERC Synergy Grant and proof of concept calls of Horizon Europe are likely to open this summer with funding allocated under the next (2022) work programme. The scientific council expects the call schedule to be back to more familiar dates by the summer of 2022.

Applicants in the UK and countries associated with Horizon 2020 will be eligible to apply on a conditional basis even though the Horizon Europe association agreements are not yet in place.

Please see the Europa website and the EU Unit Portal for recent webinars and recordings, additional ERC guidance notes and the latest on Horizon Europe.

Other Horizon Europe work programmes and calls (including collaborative R&D calls) to launch from April 2021 please see Horizon Europe draft work programmes for proposed call topics and draft funding calendars (*for internal circulation only*) on the EU Unit Portal to support engagement with your EU partners.

In the meantime, the EU team is available to answer your pre or post-award queries.

NIHR funding

- 20/142 Prehabilitation: Living with and beyond cancer
  Closes: 13:00 on 30 March 2021
  NIHR is accepting Stage 1 applications for this funding opportunity.

- 20/136 Public Health Research Programme researcher-led
  Closes: 13:00 on 30 March 2021
  The Public Health Research Programme are accepting stage 1 applications to their researcher-led workstream.

- 20/135 Continuing priority research topics of interest to the PHR Programme
  Closes: 13:00 on 30 March 2021
  The Public Health Research Programme are accepting stage 1 applications to their commissioned workstream for this topic.

- 20/120 Food taxes and subsidies
  Closes: 13:00 on 30 March 2021
  The Public Health Research Programme (PHR) accepting stage 1 applications to their commissioned workstream for this topic.

- 20/121 Indoor air quality
  Closes: 13:00 on 30 March 2021
  The Public Health Research Programme (PHR) accepting stage 1 applications to their commissioned workstream for this topic.

- 20/122 Multi-agency approaches to tackling illicit tobacco
  Closes: 113:00 on 30 March 2021
  The Public Health Research Programme (PHR) accepting stage 1 applications to their commissioned workstream for this topic.

- 20/126 Imaging in paediatric osteomyelitis *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/127 Occupational advice initiated prior to planned surgery for lower limb joint replacement *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/128 Routine measurement of gastric residual volume in paediatric critical care *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/129 Routine measurement of gastric residual volume in neonatal critical care *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/130 Intensive Interaction for children and young people with profound and multiple learning disabilities *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/131 Corticosteroid induction regimens for children and young people with juvenile idiopathic arthritis *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/132 Sexual health promotion for people with severe mental illness *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/133 Pre-operative exclusive enteral nutrition for Crohn's disease *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- 20/134 Psychological intervention for treatment-resistant generalised anxiety disorder in older adults *Australian collaborations welcome*
  Closes: 13:00 on 31 March 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream for this primary research topic.

- Programme Grants for Applied Research - Competition 35
  Closes: 13:00 on 7 April 2021
  Applications are invited for Stage 1 proposals to develop programmes of applied health research.

- 20/124 – Adult Community Health and Social Care services to avoid planned and unplanned hospital admissions
  Closes: 13:00 on 13 April 2021
  The Health Services and Delivery Research (HS&DR) Programme are accepting stage 1 applications to this call via the commissioned workstream.

- 20/143 Efficacy and Mechanism Evaluation Programme researcher-led
  Closes: 13:00 on 13 April 2021
  The Efficacy and Mechanism Evaluation Programme is accepting stage 1 applications to their researcher-led workstream.

- 20/139 - Mechanisms of action of health interventions (pilot call of expanded remit)
  Closes: 13:00 on 13 April 2021

The Efficacy and Mechanism Evaluation Programme is accepting stage 1 applications to their commissioned workstream for this funding opportunity.

- 21/13 Health Services and Delivery Research Programme (standard researcher-led)
  Closes: 13:00 on 13 April 2021
  The Health Services and Delivery Research (HS&DR) Programme are accepting stage 1 applications to their researcher-led workstream.

- 21/02 Health Technology Assessment Programme Researcher-led (evidence synthesis)
  Closes: 13:00 on 5 May 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their researcher-led workstream.
- 21/01 Health Technology Assessment Programme Researcher-led (primary research)
  Closes: 13:00 on 5 May 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their researcher-led workstream.

- 20/109 Shorter vs longer fixed-course antibiotic treatments
  Closes: 13:00 on 5 May 2021
  The Health Technology Assessment Programme is accepting stage 1 applications to their commissioned workstream, in the areas of primary research and evidence synthesis.

- NIHR Global Health Research Units
  Closes: 13:00 on 18 May 2021
  These awards will provide funding to a well-established, equitable research partnership or network of universities and research institutes in LMICs and the UK with an existing track record of delivering internationally recognised applied global health research.

- NIHR Global Health Research Groups
  Closes: 13:00 on 18 May 2021
  These awards will provide funding to collaborations of specialist researchers within universities and research institutes in LMICs and the UK who wish to establish new programmes of applied health research.

- 21/10 Health Services and Delivery Research Programme (Standard Researcher-led)
  Closes: 13:00 on 3 June 2021
  The Health Services and Delivery Research (HS&DR) Programme are accepting stage 1 applications to their researcher-led workstream.

- 21/09 Health Service and Delivery Research Programme (Evidence Synthesis Researcher-led)
  Closes: 13:00 on 3 June 2021
  The Health Services and Delivery Research (HS&DR) Programme is accepting stage 2 evidence synthesis applications to their researcher-led workstream.

- 21/04 Children and young people's mental health
  Closes: 13:00 on 3 June 2021
  The Health Services and Delivery Research (HS&DR) Programme are accepting stage 1 applications to their researcher-led workstream, for this highlight notice.

- 20/115 Health and social care workforce
  Closes: 13:00 on 3 June 2021
  The Health Services and Delivery Research Programme is accepting stage 1 applications for this funding opportunity.

Information on all NHIR funding can be found on the NIHR Funding website.

Research professional

Research Professional (formerly Research Research) has an easy-to-use sign-up process: http://www.researchprofessional.com/

Funding information: Up-to-the minute-information about all types of research funding can be found on the Research Professional website – to access this click here (account and password required).