

## Update on COVID-19 research in Suffolk and NE Essex – 04/02/2021

### COVID-19 Research findings and updates:

#### Novavax vaccine proves to be 89.3% effective

As you would have heard from the media news, the Novavax vaccine COVID-19 trial interim analysis showed positive results for the vaccine to be 89.3% effective at preventing COVID-19, including effectiveness against the new variants. The Novavax study is the largest COVID-19 vaccine trial undertaken in the UK, which recruited over 15,000 participants from 35 research UK sites in just over two months. Huge thanks go to staff at the Norfolk and Norwich, East Suffolk and North Essex NHS Foundation Trusts and all other teams in the Easter region (including Primary Care teams) in supporting the trial locally and their contribution to the success of getting the fourth vaccine to be hopefully soon approved by the regulators. Read more [here](#).

The [PRINCIPLE study](#) interim data analysis found no benefit of the commonly used antibiotics, Azithromycin and Doxycycline, on reduction of recovery time for patients in the community. Azithromycin and doxycycline were investigated as separate treatments in the PRINCIPLE trial to see if they help people with early stage COVID-19 to recover more quickly at home, or prevent the need for hospital admission. Both drugs are being used by some doctors in the hope of treating COVID-19 in the early stages of the disease. Following interim analyses of data from both the azithromycin and doxycycline arms of the study, the independent Trial Steering Committee concluded that there is no beneficial effect in patients aged over 50 who are treated with either antibiotic at home in the early stages of COVID-19. Read more [here](#). The trial is currently evaluating inhaled budesonide (a commonly used inhaled corticosteroid) vs usual care.

[The VirusWatch](#) team has released a new set of preliminary findings and you can [read these in full on their website](#). These results will also be shared with all 45,000+ participants that are taking part in the study.

[Genetic mechanisms of critical illness in Covid-19](#) – article in *Nature* journal on the initial findings from the **GenOMICC-COVID-19 study**, identifying robust genetic signals relating to key host antiviral defence mechanisms, and mediators of inflammatory organ damage in Covid-19. Read also [the study latest newsletter](#) to find out how the study is progressing and how to take part.

[RECOVERY trial closed recruitment to convalescent plasma treatment for patients hospitalised with COVID-19](#). Convalescent plasma has been widely used as a treatment for COVID-19 but to date there has been no convincing evidence of the effect of convalescent plasma on clinical outcomes in patients admitted to hospital with COVID-19. On the advice of the trial independent Data Monitoring Committee (DMC), recruitment to the convalescent plasma arm of the RECOVERY trial has now closed. The DMC saw no convincing evidence that further recruitment would provide conclusive proof of worthwhile mortality benefit either overall or in any pre-specified subgroup. Recruitment to all other treatment arms: tocilizumab, aspirin, colchicine, and Regeneron's antibody cocktail continues.

**Baricitinib – an anti-inflammatory treatment for rheumatoid arthritis** is now added to be the tenth potential COVID-19 treatment to be tested through RECOVERY trial. There is some clinical trial evidence that baricitinib may be beneficial against COVID-19. Read more [here](#).

**RECOVERY webinar with patient and doctor on Thursday 25 February from 7pm to 7.45pm** will feature Katherine Millbank, a patient who took part in the trial at Stoke Mandeville Hospital in March and April 2020, and Dr Raha West, Principal Investigator, in conversation. Katherine was recruited by Dr West to the dexamethasone arm of the trial, which was found to improve survival for hospitalised patients. To join the webinar please [complete this form to register your attendance](#).

### **New studies and studies looking for new sites:**

**New! [CLARITY ImpaCt of bioLogic therapy on SARS-cov-2 Infection and immunity study](#)** opened to recruitment at East Suffolk and North Essex NHS Foundation Trust. This study will investigate the impact of specific drugs and shielding on COVID-19 infection and subsequent immunity. The results of this study will help inform public health policy decisions for patients with IBD as well as millions of other UK patients treated with immunosuppressive drugs.

### **New! [World's first COVID-19 vaccine alternating dose study launches in UK](#)**

**The Com-Cov - COVID-19 Heterologous Prime Boost study**- the world's first COVID-19 to determine the effects of using a different approved vaccine for the second dose to the first dose, in addition to examining the efficacy of two different time intervals between doses. Over 800 volunteers, aged 50-years-old and above, are expected to take part in the study at eight sites across England - including in Oxford, London, Birmingham, Liverpool, Nottingham, Bristol and Southampton.

**[The VIVALDI Study](#)** looking for more care homes to participate. The aim of the study is to find out how many care home staff and residents have been infected with COVID-19, to inform decisions around the best approach to COVID-19 testing in the future. Initial tests will be repeated over time to learn how COVID-19 spreads in care homes and how long the antibody response lasts and whether this helps to prevent re-infection with the virus. Information collected, including vaccination data, will also link to national data on hospital admissions and deaths.

Organisations in the Eastern with links to Care Homes who would like more information about how to support this study should contact Ruth or Luke via [covid19.eastern@nihr.ac.uk](mailto:covid19.eastern@nihr.ac.uk) The study is designed to run within the care home with care home staff. [A brief video can be shared with care homes.](#)

**[RECAP \(REmote Covid Assessment in Primary Care\)](#)** is still open for expression of interest from more practices. Several of the Eastern practices accepted on to the study have recruited and others have until this week to commence recruitment. Those who have not recruited will be removed from the study.

### **Other news of interest**

**[A symptoms-based guide developed to help clinicians, and the parents of children with respiratory infections](#)** developed by researchers from the Universities of Bristol, Manchester, Oxford, and York will help clinicians and parents decide when to seek medical advice or when to treat children at home

**[End-of-life care during COVID-19: opportunities and challenges for community nursing](#)** –an article published by researchers from the Primary Care Unit, the University of Cambridge, describing how radical changes in delivery models for end-of-life care and palliative care in the community have impacted on community nursing during the pandemic.

The tables below give an overview of all COVID-19 research activity across Suffolk. Please note that this information is provided for reference only and not for external publication.

## Primary Care Studies

	Study Title	Study aim	Study setting	Local status		Recruitment <sup>1</sup>
1.	<b>Principle:</b> Platform randomised trial of Interventions against Covid-19 with older people <a href="https://www.phctrials.ox.ac.uk/principle-trial">https://www.phctrials.ox.ac.uk/principle-trial</a>	To test different medications to see whether this reduces the need for hospitalisation or will speed up recovery in older patients (65+ or 50-64 with a pre-existing condition) <b>hydroxychloroquine</b> – recruitment paused <b>Azithromycin</b> – recruitment started Other medications may be added to the trial at a later point.	Primary Care	<b>Sites activated:</b> <b>Suffolk:</b> The Peninsula Practice; The Two Rivers; Victoria Surgery The Christmas Maltings & Clements Practice Chesterfield Drive Haven Health Derby Road	<b>NEE:</b> Colchester Medical Practice Castle Gardens Medical Centre; Parsons Health Medical Centre; Shrub End Surgery; Wimpole Rd Surgery; Great Bentley Surgery Ambrose Group Ardleigh Colne Medical Practice West Mersea Rowhedge Riverside	56 across Suffolk & NEE practices  Nationally: 4,006
2.	<b>FLU-CATS:</b> Evaluation and refinement of pandemic influenza community assessment tools	An observational study of pandemic influenza community assessment tools which is being amended to pick up COVID-19 patients	Primary care	Awaiting revised protocol for COVID-19		Not yet set up
3.	<b>VIVALDI</b> COVID-19 in care homes	An observational study to understand SARS-COV-2 infection immunity and its duration in care home staff and residents in the UK	Care Homes	3 care homes in Suffolk / NEE are signed up.		North Court Care Home: 26 Catchpole Court Care Home: 36 Kingfisher House Care Home: 50  Nationally: 5,502

<sup>1</sup> Data collected from national research database – figures may lag behind actual figures

4.	<b>RECAP (REmote Covid Assessment in Primary Care).</b>	This research aims to develop a score for GPs to use when assessing how badly a patient is affected with COVID, to use over the phone or by video.	GPs and practices	Being set up across UK and Eastern	No recruits showed yet
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### Cross Sector Studies

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>2</sup>
1	Chloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study ( <b>COPCOV</b> ) <a href="http://copcov.org/">http://copcov.org/</a>	The aim of the study is to determine if hydroxychloroquine prophylaxis prevents symptomatic COVID-19 infection in front-line health care workers.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	East Suffolk and North Essex NHS Foundation Trust selected to participate;  WSH in set-up	MHRA approved study to restart  Nationally recruited: 88
2.	<b>CROWN CORONATION</b> Chloroquine Repurposing to healthWorkers for Novel Coronavirus mitigation <i>Study being amended to look at other prophylactic treatments instead of chloroquine / hydroxychloroquine</i>	The aim of the study is to determine the effectiveness of chloroquine/hydroxychloroquine prophylaxis in preventing symptomatic COVID-19 in healthcare workers at risk of SARS-CoV-2 exposure.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	ESNFT expected to take part	Not yet set up
3.	<b>Virus Watch</b>	An observational study into understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour.	All sectors expected to be involved in collection of serum samples for participating households in Part 2 of the study. Part 1 is managed centrally	Colchester Medical Practice Howard House Surgery Oakfield Surgery Stowhealth The Chesterfield Drive Practice	Colchester Medical Practice: 79 Howard House Surgery: 36 Leiston Surgery: 71 Oakfield Surgery: 22 Stowhealth: 84 The Chesterfield Drive Practice: 82  Nationally recruited: 46,223

<sup>2</sup> Data collected from national research database – figures may lag behind actual figures

4.	Multi-centre European study of MAJOR Infectious Disease Syndromes ( <b>MERMAIDS</b> ): Acute Respiratory Infections in Adults	An observational study aims to identify host and pathogen related determinants of severity of community acquired acute respiratory infections in adults.	This study will enrol participants in both primary care and secondary care.	Trusts invited for expression of interest	Not yet set up  Nationally: 47
5.	Behavioural Activation in Social Isolation ( <b>BASIL-C19</b> )	This study is part of the MODS (Multi-Morbidity in Older adults with Depression Study) programme, looking at whether a talking treatment called Behavioural Activation (BA) can help improve a person's physical and psychological functioning, for example self-care and mood. The study is asking 'can we prevent or ameliorate depression and loneliness in older people with long term conditions who are under enforced COVID-19 isolation?'	Looking for Trust sites; with potential cross-sector involvement with primary care	Trusts invited for expression of interest	Not yet set up
6.	Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes ( <b>PHOSP-COVID</b> )	The aim is to understand and improve long-term outcomes for survivors of hospitalisation with COVID-19. The PHOSP-COVID study is aligned to the clinical follow-up provided, but does not alter clinical care.	TBC	TBC	Not yet set up
7.	<b>Psychological Impact of COVID-19</b>  <b>N.B. the study adopted on NIHR portfolio but not badged with urgent public health status</b>	A survey to explore the psychological impact of COVID-19 outbreak and the resultant restrictions in terms of behavioural, emotional and social factors.	Advertised through social media via local Trusts and CCGs	Norfolk & Suffolk NHS foundation Trust (NSFT)	NSFT: 104
8.	<b>Novavax COVID Vaccine study</b> – A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine	12-month placebo controlled trial to evaluate the safety and efficacy of the Novavax Vaccine in adults 18-84.	Study based at ESNEFT and supported by Primary Care team	ESNEFT; <b>recruitment completed</b>	ESNEFT: 168  Nationally: 15,203

### Secondary Care Studies

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>3</sup>
1.	<b>RECOVERY:</b> Randomised Evaluation of COVID-19 Therapy	To test if existing or new drugs can help patients hospitalised with confirmed COVID-19; The UK New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) advised that several possible treatments should be evaluated, including: <b>Lopinavir-Ritonavir</b> (arm closed-shown no clinical benefit; read more <a href="#">here</a> ), <b>Interferon <math>\beta</math>, corticosteroids<sup>4</sup>, and Remdesivir, Hydroxychloroquine</b> (arm closed; read more <a href="#">here</a> ), <b>Tocilizumab, Dexamethasone, convalescent plasma</b> . Other treatments may soon emerge that require evaluation. The supply arrangements for each medicine for RECOVERY trial are described <a href="#">here</a> .	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 131 Ipswich Hospital: 334  Nationally: 34,342
2	<b>RECOVERY-RS (Respiratory support)</b>  <a href="https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/">https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/</a>	This study is aiming to determine if CPAP (continuous positive airway pressure) or HFNO (high flow nasal oxygen) is clinically effective compared to standard care (excluding CPAP or HFNO).	Secondary care	Open sites: Ipswich Hospital Colchester WSH	ESNEFT:8  Nationally: 1,037
3.	<b>Re-MAP Cap:</b> Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia  <a href="https://www.remapcap.org/">https://www.remapcap.org/</a>	The trial will look at a number of different treatment categories with an aim to determine the best clinically effective treatment for adult patients with CAP admitted to participating intensive care units with suspected or microbiological testing confirmed COVID-19 infection.	Secondary care/ICUs	All sites running RECOVERY study are invited to participate	ESNEFT:32  Nationally: 3,996
4.	<b>CCP-UK</b> Clinical Characterisation Protocol for Severe Emerging Infection' study/(ISARIC-4C)	An observational study collecting samples and data from confirmed COVID-19 patients	Secondary care	All acute Trusts in the Eastern region activated;	ESNEFT: 2426 WSH: 983  Nationally: 172,323

<sup>3</sup> Data collected from national research database – figures may lag behind actual figures

<sup>4</sup> Corticosteroids used in the trial are expected to be sourced by local pharmacy procurement team via their normal routes, all other medications for RECOVERY sourced centrally via PHE

5.	<b>UKOSS:</b> Pandemic Influenza in Pregnancy <a href="https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy">https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy</a>	An observational study via the UK Obstetric Surveillance System to collect information on pregnant women admitted to hospital with confirmed COVID-19	Secondary care / Trusts with Maternity Units	Open sites: Colchester; Ipswich hospitals; WSH	No recruitment data showing
6.	<b>GenOMICC</b> Genetics of susceptibility and mortality in critical care	An observational study to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury.	Secondary care	Ipswich Hospital open WSH reviewing	Ipswich Hospital: 64 WSH:1  Nationally: 9,657
7.	Coronavirus infection in primary or secondary immunosuppressed children.	An observational study designed to allow families of immunosuppressed children and young people to self-record their experiences of COVID-19 and other viral respiratory illnesses during the COVID-19 epidemic.	Secondary care	Not open to new sites currently	<b>Recruitment now complete</b>  Nationally recruited: 1,633
8.	<b>PAN COVID</b> : Pregnancy and Neonatal Outcomes in COVID-19 <a href="https://pan-covid.org/">https://pan-covid.org/</a>	A global registry of women with suspected or confirmed SARS-CoV-2 infection in pregnancy and their neonates, understanding natural history to guide treatment and prevention	Secondary care	Open sites: WSH ESNFT (Ipswich & Colchester)	ESNEFT: 36 West Suffolk:3  Nationally: 5,984
9.	Neonatal Complications of Coronavirus Disease (COVID-19) Study	This is a national surveillance programme using the standard British Paediatric Surveillance Unit (BPSU) approach. This study will run alongside and be cross-linked with the maternal surveillance study run through the United Kingdom Obstetric Surveillance System (UKOSS; CPMS: 14162), which is already in progress.	Secondary care	Open sites: WSH	There will be no consenting (no recruits) for this study as linked to another study

10.	<b>TACTIC-R</b> (Multiarm Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs)	The TACTIC-R clinical trial is testing whether existing drugs, which are already used to treat other immune-related conditions, can prevent the development of severe symptoms in patients hospitalised with confirmed/strongly suspected COVID-19. This approach, known as repurposing, is a way of finding out whether existing therapies, which are likely to be readily available in hospitals, are effective in treating the disease.	Secondary care	Several sites in Eastern are being set up  Opened sites: WSH	WSH: 20  Nationally recruited: 392
11.	<b>SIREN</b> : Sarscov2 Immunity & REinfection EvaluationN - The impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers	An observational study which aims to find out whether healthcare workers who have evidence of prior COVID-19 infection, detected by antibody assays (positive antibody tests), compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection. For SARS CoV2 infection it is not yet known if the detection of antibodies protects people from future infection. This study aims to provide this very important information, which will help to understand the future impact of COVID-19 on the population.	Secondary care	Currently is being set up in secondary care – all trusts expected to take part as part of Trust wide antibody screening processes  Open sites: WSH ESNEFT	WSH: 484 ESNEFT: 350  Nationally recruited: 32,993
12	<b>NHS CHECK</b> : Health & Experiences of staff working at NHS Trusts and Nightingale Hospitals <a href="https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff">https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff</a>	Aims to establish a cohort of NHS-affiliated staff to investigate the short, medium and longer term psychosocial impact of the COVID-19 pandemic on staff performance and wellbeing. NHS staff will be invited to participate, to complete an online survey module and an intervention evaluation module	Secondary care	Open sites: ESNEFT	ESNEFT: 425  Nationally recruited: 25,694

13.	<a href="#">What's the STORY?</a>	This Oxford Vaccine Group study is investigating the serological profile of children and young adults to assess how well the population is protected from vaccine preventable disease. This study will involve blood sampling from people aged from birth to 24 years of age to look at their antibody levels against important infectious diseases.	Secondary care	Opened at: West Suffolk Hospital	WSH: 1  Nationally: 2,086
14.	<b>New!</b> <a href="#">CLARITY ImpaCt of bioLogic therApy on saRs-cov-2 Infection and immunity</a>	This study will provide an evidence base for safer prescribing of immunomodulator and biologic drugs in the COVID-19 era and inform public health policy regarding physical distancing measures, and future vaccination strategies. Although this study will define risk in IBD (Inflammatory Bowel Disease) patients, there are potentially important lessons to be learned for other patients across with other immune mediated diseases treated with similar therapies.	Secondary care	Open at ESNEFT	ESNEFT: 29  Nationally: 7,206

<sup>5</sup>Local update

A full list of all DHSC priority COVID-19 studies can be found at <https://www.nihr.ac.uk/covid-studies/>