Department of Health & Social Care

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13 May 2020

Dear Colleagues

Early phase COVID-19 trials

As you know, DHSC has issued guidance on the impact of COVID-19 on research funded or supported by NIHR which is available on the NIHR website https://www.nihr.ac.uk/covid-19/. On 7 May the CMOs in the UK and NHSE Medical Director wrote to the NHS about recruiting patients into COVID-19 clinical trials. Their letter highlighted the importance of early phase trials alongside the existing phase III platform trials and an expectation that recruitment for the early phase studies be focused on more specialist centres across the UK, especially those with NIHR Biomedical Research Centres in England or centres in the devolved nations with experience of such trials.

Following discussions with colleagues across the NIHR early translational infrastructure, I am writing to provide clarity on the prioritised status of these early phase trials and expectations on how these might be supported.

The Department has agreed with colleagues in UK Research and Innovation (UKRI) through the Therapeutics Taskforce that the early phase (PII) platform trials ACCORD2, CATALYST, TACTIC and DEFINE will not need to be reviewed via the Urgent Public Health Research Panel, but will be identified as having Urgent Public Health Research status. These platforms will be listed as such on the NIHR website from 11 May 2020. Please note this status applies only to the therapeutic candidates which have been identified by the Phase II Prioritisation Panel (chaired by Prof Patrick Chinnery) and have regulatory approval.

Chief Investigators for each of the platforms have reached agreement on which platforms individual sites hosting NIHR BRC/CRFs will be supporting to avoid overlap as far as possible. The NIHR Respiratory Translational Research Collaboration has been heavily involved in co-ordinating this. Whilst there is no expectation that individual NIHR BRC/CRFs support more than one of these platforms, if you are asked and have capacity to do so we would welcome this to ensure we are maximising our ability to deliver these nationally prioritised studies at pace.

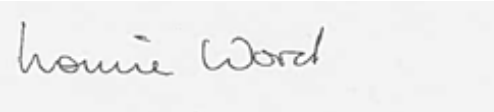
We expect sites which host NIHR BRC/CRFs to prioritise recruitment to these studies and that the support costs will be made available from the NIHR BRC and/or CRF award. We recognise that it may not always be possible to recruit fully to these early phase trials at the NHS Trusts hosting

NIHR BRC/CRFs and it may be necessary to include other sites, for which the NIHR Clinical Research Network (CRN) will cover the NHS support costs. In order to do so it's vital that there is an agile and co-ordinated process led by the CRN which takes into account live data on COVID-19 admissions across the country and competing studies at sites. CI/PIs (or CROs acting on behalf of the relevant platform) should contact Divya.chadhamanek@nihr.ac.uk at the NIHR CRN for assistance in rapid site selection and set up and arrangement of adequate provision for the NHS support costs at these sites.

May I take this opportunity to restate our position that all NIHR infrastructure award holders have the flexibility within their existing contracts to redeploy their existing resource within their funding award to support COVID-19 research activity, provided this activity is aligned to remit of the infrastructure award and their approved research themes. NIHR BRCs can make local decisions about supporting other early translational COVID-19 research activity provided this does not impact on the NHS Trust's ability to support nationally prioritised research activity, including those detailed in this letter.

Thank you for your continuing support with this endeavour in challenging circumstances.

Best wishes



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Copy:

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UKRI: Sir Mark Walport, Prof Patrick Chinnery, Dr Glenn Wells, Dr Alison Cave
NIHR: Dr Jonathan Sheffield, Prof Nick Lemoine, Dr Matthew Hallsworth, Dr Jane Luff, Divya Chadhamanek
Therapeutics Task Force: Charlotte Taylor