

LETTER TO THE EDITOR

Response to Dal-Ré and Holm's ethical concern regarding the UK PANORAMIC COVID-19 trial by the PANORAMIC Investigators

Dear Editor,

Dal-Ré and Holm question the ethical basis of the PANORAMIC trial because of concerns that participants may be denied access to treatments available from the NHS Covid Medicines Delivery Units (CMDUs).¹ All participants are able to receive standard best available care (outside of the trial), regardless of whether they receive an antiviral in PANORAMIC or not. If randomized to an anti-viral arm in PANORAMIC, participants who are eligible for CMDU treatment can also be given a neutralizing monoclonal antibody (nMAB) or an antiviral drug outside of PANORAMIC. This is all at the discretion of the clinician in charge at the CMDU. Similarly, if randomized to Usual Care in PANORAMIC, participants can still receive an nMAB or an antiviral agent from a CMDU. Our analysis plan takes this into account. The PANORAMIC Trial Website states that some may be eligible to receive antiviral treatment outside of the PANORAMIC Trial and that their clinical care remains under the direction of the NHS.

The CDMUs were established to provide access to acute COVID treatments for the highest risk patients, a much smaller eligible population than all people over 50 or over 18 with a COVID risk factor eligible for PANORAMIC. The care pathways are complementary. Further, highest risk patients have been contacted with advice (and a PCR test kit) how to access a CDMU in the event they become infected and CDMUs are also contacting eligible people at highest risk if they test positive.

Molnupiravir has conditional marketing approval in the UK, recognizing that clinical data for full authorization are not yet available. PANORAMIC is a key contribution to generate these data. For example, participants in the pivotal phase 3 trial (MOVE-OUT) were unvaccinated, exposed to different variants of SARs-CoV-2 from those in current circulation, and largely recruited in healthcare systems different from the UK. It is important to evaluate whether


the treatment effect on which the conditional approval is based applies in a clinically relevant population in the UK. PANORAMIC thus represents a pragmatic means to assess molnupiravir and other potential treatments without denying participants access to treatments available through other approved routes.

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COMPETING INTERESTS

CC Butler and the PANORAMIC Trial Investigators are part of the PANORAMIC Trial.

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REFERENCE

1. Dal-Ré R, Holm S. Ethical concern regarding the UK PANORAMIC COVID-19 trial. *British Journal of Clinical Pharmacology*. 2022;1-2. doi: [10.1111/bcp.15275](https://doi.org/10.1111/bcp.15275)