

#### South Central - Berkshire Research Ethics Committee

Bristol REC Centre Temple Quay House 2 The Square Temple Quay Bristol BS1 6PN

06 April 2022

Study title: Platform Adaptive trial of NOvel antiviRals for eArly

treatMent of covid-19 In the Community

REC reference: 21/SC/0393
Protocol number: PANORAMIC
EudraCT number: 2021-005748-31

Amendment number: Substantial Amendment 03

Amendment date: 01 April 2022 IRAS project ID: 1004274

The above amendment was reviewed by the Sub-Committee in correspondence.

## **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

## **Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Amendment Summary [AmendmentSummary]		05 April 2022
Annex 2: Notification of Amendment/Amendment tool [Amendment Tool]	1.0	01 April 2022
Cover Letter [Regulatory Cover Letter]	1.0	05 April 2022
Investigator Brochure/SmPC [Paxlovid Summary of Product Characteristics]	Updated on EMC website 02/03/2022	02 March 2022
Participant information and informed consent form [Paxlovid PIS Appendices TRACKED]	2.0	01 April 2022
Participant information and informed consent form [Paxlovid PIS Appendices CLEAN]	2.0	01 April 2022
Participant information and informed consent form [Virology Participant Instructions Less Intensive Sampled Cohort TRACKED]	2.0	01 April 2022
Participant information and informed consent form [Virology Participant Instructions Less Intensive Virology Sampled Cohort CLEAN]	2.0	01 April 2022
Participant information and informed consent form [Virology Participant Instructions Intensive Virology Sampled Cohort TRACKED]	2.0	01 April 2022

Participant information and informed consent form [Virology Participant Instructions Intensive Virology Sampled Cohort CLEAN]	2.0	01 April 2022
Participant information and informed consent form [Molnupiravir PIS Appendices CLEAN]	3.0	01 April 2022
Participant information and informed consent form [Molnupiravir PIS Appendices TRACKED]	3.0	01 April 2022
Project Information - PDF [ProjectStudyInformation]		05 April 2022
Protocol [Protocol TRACKED]	3.0	01 April 2022
Protocol [Protocol CLEAN]	3.0	01 April 2022
REC Application Form [Ethics]		05 April 2022

#### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

#### **Working with NHS Care Organisations**

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

#### **Amendments related to COVID-19**

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### **HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities— see details at: <a href="https://www.hra.nhs.uk/planning-and-improving-research/learning/">https://www.hra.nhs.uk/planning-and-improving-research/learning/</a>

IRAS Project ID - 1004274:

Please quote this number on all correspondence

Yours sincerely



**Mr David Carpenter** 

# Chair

E-mail: berkshire.rec@hra.nhs.uk

Enclosures: List of names and professions of members who took part in the

review

Copy to:

# South Central - Berkshire Research Ethics Committee Attendance at Sub-Committee of the REC meeting on 15 April 2022

# **Committee Members:**

Name	Profession	Present	Notes
Mr David Carpenter	Retired Social Scientist	Yes	
Dr Mike Proven	University Research Governance Officer	Yes	