Health Research Authority

London - Riverside Research Ethics Committee

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Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

28 May 2019

RAMPART Trial Management Team
MRC Clinical Trials Unit at UCL
90 High Holborn
WC1V 6LJ

Dear Trial Management Team

Study title:	**Renal Adjuvant MultiPle Arm Randomised Trial (RAMPART): An international investigator-led phase III multi-arm multi-stage randomised controlled platform trial of adjuvant therapy in patients with resected primary renal cell carcinoma (RCC) at high or intermediate risk of relapse**
REC reference:	**17/LO/1875**
Protocol number:	**RE06**
EudraCT number:	**2017-002329-39**
Amendment number:	**06**
Amendment date:	**18 April 2019**
IRAS project ID:	**219487**

Approval was sought for the following:

1) The main reason for amending the Protocol and its supporting documents is to reflect new information provided in the most recent version of the Durvalumab Investigator Brochure (v14.0, February 2019).

2) The updated Investigator Brochure identified several new Adverse Events of Special Interest (AESIs), which we have now incorporated into the Protocol. There were also changes to the Reference Safety Information (RSI) – both new expected side-effects and changes to the frequency of those previously listed – and we are keen to ensure patients are being adequately informed of these risks through an updated Participant Information Sheet.

The above amendment was reviewed at the meeting of the Sub-Committee held on 16 May 2019 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*
Covering letter on headed paper [HRA Cover Letter 18-Apr-2019.pdf]		18 April 2019
Investigator's brochure / IMP Dossier [Durvalumab IB v14.0 11-Feb-2019.pdf]	V14.0	11 February 2019
Investigator's brochure / IMP Dossier [Tremelimumab IB v9.0 27-Nov-2018.pdf]	v9.0a	27 November 2018
Notice of Substantial Amendment (CTIMP) [Notification of Substantial Amendment Form 18-Apr-2019.pdf]	06	18 April 2019
Other [RAMPART Summary of Changes from RAMPART Protocol v1.0 to v2.0.pdf]		
Participant consent form [RAMPART Consent Form v2.0 18-Apr-2019 (clean).pdf]	v2.0	18 April 2019
Participant consent form [RAMPART Consent Form v2.0 18-Apr-2019 (tracked).pdf]	v2.0	18 April 2019
Participant consent form [RAMPART Partner Consent Form v2.0 18-Apr-2019 (clean).pdf]	2.0	18 April 2019
Participant consent form [RAMPART Partner Consent Form v2.0 18-Apr-2019 (tracked).pdf]	2.0	18 April 2019
Participant information sheet (PIS) [RAMPART Participant Information Sheet v2.0 18-Apr-2019 (clean).pdf]	v2.0	18 April 2019
Participant information sheet (PIS) [RAMPART Participant Information Sheet v2.0 18-Apr-2019 (tracked).pdf]	v2.0	18 April 2019
Participant information sheet (PIS) [RAMPART Pregnant Partner Information Sheet v2.0 18-Apr-2019 (tracked).pdf]	2.0	18 April 2019
Participant information sheet (PIS) [RAMPART Pregnant Partner Information Sheet v2.0 18-Apr-2019.pdf]	2.0	18 April 2019
Research protocol or project proposal [RAMPART Protocol v2.0 18-Apr-2019 (tracked).pdf]	2.0	18 April 2019
Research protocol or project proposal [RAMPART Protocol v2.0 18-Apr-2019.pdf]	2.0	18 April 2019
Sample diary card/patient card [RAMPART Patient Card (Arm A) v1.0 18-Apr-2019.pdf]	1.0	18 April 2019
Sample diary card/patient card [RAMPART Patient Card (Arm B & C) v1.0 18-Apr-2019.pdf]	1.0	18 April 2019

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.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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: https://www.hra.nhs.uk/planning-and-improving-research/learning/

17/LO/1875:	**Please quote this number on all correspondence**

Yours sincerely

Pp Approvals Officer

Dr Margaret Jones
Chair

E-mail: nrescommittee.london-riverside@nhs.net

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

Copy to: *James Larkin, Royal Marsden Hospital*

London - Riverside Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 16 May 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Stephanie Ellis BEM	Former Civil Servant	Yes	
Dr Margaret Jones (Chair)	Retired General Practitioner	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Stephan Ramey	Approvals Administrator