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Regulating Medicines and Medical Devices

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MEDICAL RESEARCH COUNCIL CLINICAL TRIALS UNIT
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24/11/2017

Dear Prof M Parmar

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	20363/0380/001-0001
Eudract Number:	2017-002329-39
Product:	Durvalumab
Protocol number:	RE06

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority accepts your amended request for a clinical trial authorisation (CTA), received on 23/11/2017.

Remark: the Sponsor should amend the table of contents at the time of the next protocol amendment (for example the titles of the appendices are not correct, the links do not work properly, etc).

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed; changes made as part of your amended request may need to be notified to the Ethics Committee.

Yours sincerely,

Clinical Trials Unit
MHRA