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Mr O Schofield
UNIVERSITY COLLEGE LONDON
CANCER RESEARCH UK AND UCL CANCER TRIALS CENTRE
90 TOTTENHAM COURT ROAD
LONDON
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UNITED KINGDOM

09/02/2018

Dear Mr O Schofield

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031 (as amended)(the 'Regulations')

Our Reference:	20363/0386/001-0001
Eudract Number:	2017-002544-32
Product:	Opdivo
Protocol number:	UCL/15/0515

NOTICE OF GROUNDS FOR NON-ACCEPTANCE AND RIGHT TO AMEND REQUEST

I refer to your request for a clinical trial authorisation (CTA), received on 26/01/2018. The Licensing Authority has carefully considered your request in accordance with regulations 18-20 of the Regulations, but has decided that it is not acceptable at this point on the following grounds:

Grounds for Non-Acceptance
Medical Points
* An amended protocol (clean, ideally signed document) should be submitted to address the following (a commitment to submit an amended protocol before dosing the first trial participant will not be acceptable):
1) The Sponsor is required to amend the protocol and include a rationale to support both the dose and the regimen of nivolumab.
For clarification on the above points, please contact Dr Maria Beatrice Panico (beatrice.panico@mhra.gov.uk).
The Sponsor is reminded that the only changes that can be implemented at the time of the GNA response are the ones required to address the grounds of non-acceptance (GNAs) raised by the MHRA.

Pharmaceutical Point
* A revised QP declaration with the correct EudraCT number should be provided.
For further information on the above point, please contact Dr Simon Lewis on 020 3080 6621 or simon.lewis@mhra.gov.uk.

You may respond to the grounds identified in this letter within the timescales set out in regulations 18-20 [14 days for regulations 18 and 20; 30 days for regulation 19 (advanced therapy medicinal products or products containing genetically modified organisms)], otherwise your application will be deemed to have been refused. This amended request should cover all the issues raised in this letter, and only these issues.

Yours sincerely,

Clinical Trials Unit
MHRA