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Miss Karina Cox
MAIDSTONE & TUNBRIDGE WELLS NHS TRUST
HERMITAGE LANE,
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MAIDSTONE
ME16 9QQ
UNITED KINGDOM

28/07/2020

Dear Miss Karina Cox,

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

Our Reference:	CTA 21423/0204/001-0001
Eudract Number:	2020-000819-67
Product:	Sonovue
Protocol number:	MTW_2020_KC01

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 09/06/2020.

MEDICAL - Remarks: Clinical Remarks

The following comments are for future consideration / information only and do not affect the approval status of your study. No response is required.

Whilst the trial application is approved, the sponsor is reminded that there is a regulatory expectation that the risk/benefit balance will be re-evaluated as and when required whilst the COVID-19 pandemic continues.

For information on Managing clinical trials during Coronavirus (COVID-19), the sponsor is referred to the guidance provided at the MHRA website:

<https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19>

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