MHRA
Regulating Medicines and Medical Devices

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Ms E Wallis
SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
STH RESEARCH DEPARTMENT
ROYAL HALLAMSHIRE HOSPITAL, 305 WESTERN BANK
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UNITED KINGDOM

11/07/2016

Dear Ms E Wallis

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

Our reference:	21304/0259/001-0001
Eudract Number:	2015-005713-67
Product:	FRESENIUS KABI Zoledronic Acid Fresenius Kabi Infusion 4 mg/5 ml
Protocol number:	STH19171

NOTICE OF ACCEPTANCE

I am writing to inform you that the Licensing Authority accepts your request for a clinical trial authorisation (CTA), received on 13/06/2016.

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.

Yours sincerely,

Clinical Trials Unit
MHRA