MHRA
Regulating Medicines and Medical Devices

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Ms G Hamblin
LIVERPOOL HEART AND CHEST HOSPITAL NHS FOUNDATION TRUST
RESEARCH CENTRE
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UNITED KINGDOM

11/11/2016

Dear Ms G Hamblin

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

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|---|---|
| Our Reference: | 21422/0007/001-0001 |
| Eudract Number: | 2016-002832-34 |
| Product: | Cayston |
| Protocol number: | AZLI2016DN001 |

**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 01/11/2016.

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; changes made as part of your amended request may need to be notified to the Ethics Committee.

Yours sincerely,

**Clinical Trials Unit**
**MHRA**