Medicines & Healthcare products Regulatory Agency

MHRA

**MHRA**
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

**gov.uk/mhra**

Ms N Boota
UNIVERSITY OF WARWICK
WARWICK CLINICAL TRIALS UNIT, WARWICK MEDICAL SCHOOL
GIBBET HILL ROAD
COVENTRY
CV4 7AL
UNITED KINGDOM

15/08/2018

Dear Ms N Boota

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

| | |
|---|---|
| Our Reference: | 16719/0231/001-0002 |
| Eudract Number: | 2017-001785-14 |
| Product: | Landiolol hydrochloride 300 mg lyophilised powder |
| Protocol number: | STRESS-L |
| Substantial Amendment Code Number: | Code Number: SA_05 |
| Version: | |
| Date: 2018/07/31 | |

**NOTICE OF ACCEPTANCE OF AMENDMENT**

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 02/08/2018.

This amendment may therefore be made.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

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