Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA

151 Buckingham Palace Road
London
SW1W 9SZ
United Kingdom

www.gov.uk/mhra

Ms Beth Muldrew
Cambridge University Hospitals NHS Foundation Trust
Barts Clinical Trials Unit
Centre for Cancer Prevention
Queen Mary University of London
Cambridge Biomedical Campus
EC1M 6BQ
United Kingdom

Our ref: CI/2016/0057

Your ref: Amendment 8 (REC Amendment 6)

31 May 2018

Dear Ms Muldrew

CLINICAL INVESTIGATION
AMENDMENT [7] - NO OBJECTION

Manufacturer : Cambridge University Hospitals NHS Foundation Trust
Model Name : BEST3 Cytosponge
Description : "Barrett's Oesophagus Cytosponge Test Kit "

Thank you for your letter dated 20th February 2018 informing us of your intention to make the following amendments as detailed within the letter to the;

1. Randomisation method
2. Additions of the following sites
3. Changes to the Investigator brochure
4. Changes to patient information

Following the teleconference that took place on 31st May 2018 we are writing to inform you that the Competent Authority has no objection to the changes described in your letter with the following recommendations/conditions which are as follows;

1) MHRA recommends that the two parts of the study (pre and post individual randomisation) should be analysed separately based on methods that respect the structure of the data.
2) MHRA recommends to also estimate treatment effect based on a combined analysis from the two parts of the study (pre and post randomisation). A combined analysis should only be performed if the results from the two parts of the study favour the study test.

If you have not done so already and prior to implementing this study amendment MHRA require a copy of the Protocol/Clinical Investigation Plan authorisation page, with all the required signatures.

Please note that the amendment must not be implemented until the relevant Ethics Committee approval has been obtained. Ethics Committee approval forms part of the information required under Section 2.2 of Annex VIII, therefore in light of this please confirm that Ethical approval has been granted for this amendment and provide MHRA with a copy of this as soon as it becomes available.

If you have not done so already you are also required to obtain approval for the new investigation site(s) (for NHS sites this approval must be obtained from the NHS/HSC R&D office and for non-NHS sites this approval must be obtained from your ethics committee). Please notify MHRA of the outcome of the relevant approvals for each new site once received. Please note that this clinical investigation must **not** commence in any of the new UK sites until you have received the relevant approvals for that individual site and you have notified MHRA of this.

May I also take this opportunity to remind you that in the event of a serious adverse incident occurring during the course of the clinical investigation you should inform the MHRA Adverse Incident Centre in line with the requirements in our letter of No Objection.

Yours sincerely,

Sean Williams
(on behalf of the Competent Authority)

Tel: +44 (0)20 3080 7325
Email: sean.williams@mhra.gov.uk