

UNITED KINGDOM – CHINA – MALAYSIA

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MHRA

151 Buckingham Palace Road

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SW1W 9SZ **EudraCT number: 2021-003853-40**

**IRAS Project ID: 290474**

**Purchase Order Number: 4484317**

Nottingham, 19th August 2021

Dear MHRA,

Re: The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) Trial: a single-blind, randomized controlled trial of metoclopramide for the prevention of pneumonia in patients with dysphagia after an acute stroke

We are writing on behalf of the Stroke Trials Unit (STU) to notify you of the submission of the application form titled ‘The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) Trial’.

The MAPS-2 study was previously approved by MHRA (The Metoclopramide and selective oral decontamination for Avoiding Pneumonia after Stroke (MAPS-2) Trial: a 2x2 double-blind RCT of metoclopramide and selective oral decontamination for the prevention of pneumonia in patients with dysphagia after an acute stroke IRAS 207212/ ISRCTN14124645/ EudraCT2016-003406-14), but we were unable to open the study due to internal issues relating to the then sponsor (University Hospital of North Midlands) and the HTA withdrew funding, so that the study never started.

We have reapplied to HTA with a new sponsor (University of Nottingham) and regained funding. Due to problems importing the oral decontamination paste in the wake of Brexit we had to drop one arm of the study (oral decontamination). The study is otherwise essentially unchanged, now testing metoclopramide alone.

As per your guidance please find enclosed the following:

* A covering letter with highlighted Purchase Order (PO) number
* A clinical trial application form in PDF versions
* A protocol, patient information sheet and consent forms.
* The SmPC

We trust all the enclosed required supporting documentation has been completed correctly.

Yours sincerely,

Christine Roffe

Chief Investigator