## **MARCH Trial Telephone Randomisation Service**

User Guide



## Introduction

Centre for Healthcare Randomised Trials

The purpose of the MARCH Trial Randomisation Service is to allocate a treatment to participants in the MARCH Trial.

The Randomisation Service system is telephone based. As you use the system, you will be required to respond to it in one of two ways - dialling numbers on your telephone keypad, or speaking a response into the telephone handset.

To make it easier for you, the image below will clearly indicate if you will need to interact with the telephone randomisation service.

Use your telephone keypad



to enter data when prompted.

Speak into the telephone



when prompted

## Randomisation Telephone No.

0800 2802 307

## Your Trial ID Code

Your trial ID Code starts with 219XX. The last two digits of the TRIAL ID code (XX) are your CENTRE NUMBER.

Your CENTRE NUMBER will be provided by NICTU.

Please email <u>march@nictu.hscni.net</u> if you have not yet received your CENTRE NUMBER.

## **CHaRT Contact Details:**

For any problems or queries regarding with the MARCH Randomisation System, contact CHaRT Support. Available Monday to Friday 8am to 5pm Telephone 01224 43 8188 or Email <u>chart.support@abdn.ac.uk</u>

## Tel: 0800 2802 307 Part 1 – Entering the Trial ID Code

## Prompt

Welcome to the Aberdeen Trials Service. Please enter your Trial ID Code followed by the  $\star$  (star) key.

## Your response



You should respond with your 5-digit Trial ID Code For example, 21901 - then press the \* key

Your Trial ID Code is 219 XX (where XX is your two digit centre number)

Prompt

This is the MARCH trial. Your trial site is [centre name]. Press 1 to continue or 2 to modify.

## Your response



Respond by pressing 1 or 2 on the telephone keypad

## Part 2 – Supply Initials

## Prompt

Please speak the participant's initials after the tone using two letters only. Then press the  $\star$  key

## Your response



Speak participant's initials into the telephone For example, "JS" Then press the \* key





Please speak only two initials.

**Prompt (optional)** 

You said ... Press 1 to continue or 2 to modify.

## Your response

Respond by pressing 1 or 2 on the telephone keypad

## Part 3 – Gender

## Prompt

Please enter the participant's gender. Enter 1 for Male or 2 for Female.

#### Your response



You should respond by pressing 1 or 2 For example, **1** 

## Prompt (optional)

You said ... Press 1 to continue or 2 to modify.

Your response



Respond by pressing 1 or 2 on the telephone keypad

## Part 4 – Date of Birth

## Prompt

Please enter the participant's date of birth as 8 digits in the form day-day monthmonth year-year-year. For example, the date 18th February 1974 would be 18021974.

## Your response



You should respond by entering the date of birth as 8 digits. For example, the date 18<sup>th</sup> February 1974 would be **18021974** 

## Prompt (optional)

You entered ... Press 1 to continue or 2 to modify.

## Your response



Respond by pressing 1 or 2 on the telephone keypad

## Part 5 – Screening Number

## Prompt

Please enter the participant's Screening Number.

#### Your response



You should respond by entering the 6-digit Screening Number without the leading S. For example, **010001** for (**S010001**)

Prompt (optional)

You entered ... Press 1 to continue or 2 to modify.

Your response



Respond by pressing 1 or 2 on the telephone keypad

## Part 6 – Pregnancy Test

#### Prompt

Has a pregnancy test been performed, and a negative result obtained and documented?

Guidance wording:

"Not applicable should only be selected if the patient is not of child-bearing potential i.e. a biological reason precluding child-bearing potential has been documented in the notes e.g. sterilisation, hysterectomy, menopause"

Your response



You should respond by pressing 1 for Yes, 2 for No, and 3 for Not Applicable

**Prompt (optional)** 

You entered ... Press 1 to continue or 2 to modify.

Your response



## Part 7 – Confirmation of Eligibility

## Prompt

Has the patient been confirmed as eligible for recruitment? Press 1 for yes or 2 for no.

#### Your response



You should respond by pressing 1 or 2 For example, 1

**Prompt (optional)** 

You entered ... Press 1 to continue or 2 to modify.

Your response



## Part 8 – Informed Consent

#### Prompt

Has informed consent been obtained? Press 1 for yes or 2 for no.

#### Your response



You should respond by pressing 1 or 2 For example, **1** 

**Prompt (optional)** 

You entered ... Press 1 to continue or 2 to modify.

Your response



Respond by pressing 1 or 2 on the telephone keypad

## Part 9 – Allocated Participant Study Number

#### Prompt

You will now be told the participant's study number.

The study number allocated to this participant is...

Please confirm the allocated participant study number by entering it on the telephone keypad.

#### Your response



You should respond by entering the allocated participant number (without the leading R(0)) For example, **1001** for (**R01001**) or 1**1001** for (**R11001**)

## Part 10 – Confirm the Treatment

#### Prompt

The allocated Treatment is..... Please confirm the allocated treatment by pressing 1 for Carbocisteine plus Usual Airway Clearance Management,

- 2 for Hypertonic Saline plus Usual Airway Clearance Management,
- 3 for Carbocisteine and Hypertonic Saline plus Usual Airway Clearance Management.
- 4 for Usual Airway Clearance Management.

#### Your response



You should respond by pressing the key that corresponds to the allocated treatment.

For example, 1,2, 3 or 4

## Prompt

You said ... Press 1 to continue or 2 to modify.

## Your response



Respond by pressing 1 or 2 on the telephone keypad

NB Please wait to hear the following prompt before ending the call.

Part 11 – Finish
Prompt
Thank you for calling the MARCH telephone randomisation service.
Your response
Hang up.