From: "Godfrey, Dr Elaine" <Elaine.Godfrey@mhra.gsi.gov.uk>
Subject: **RE: PODCAST trial: CONFIDENTIAL**
Date: 27 April 2009 08:29:46 BST
To: "Philip Bath" <philip.bath@nottingham.ac.uk>

Dear Philip

You are correct in your assumption. Since the trial is not within the scope of the Clinical Trials Directive, the MHRA has no involvement. There are no requirements for labelling other than the usual ones applying to dispensed medicines.

Hope all goes well.

Elaine

From: Philip Bath [mailto:philip.bath@nottingham.ac.uk]
Sent: 27 April 2009 08:26
To: Godfrey, Dr Elaine
Subject: Re: PODCAST trial: CONFIDENTIAL

Dear Elaine,

Many thanks. I wonder if you could clarify a couple of points:
1. If no CTA is required, then I assume the MHRA have no 'interest' in any capacity in the trial?
2. We have no obligations regarding labeling, storage; i.e. we can simply ask that hospital doctors/GPs prescribe as usual as per the trial randomisation (intensive vs guideline).

Sorry about these questions but I have never done a trial which did not involve CSM/MHRA etc. If there is any material relevant to this sort of trial I would be grateful to know what.

Philip

On 27 Apr 2009, at 08:02, Godfrey, Dr Elaine wrote:

> Dear Philip
>
> We have had a look at this trial protocol and can confirm that no CTA will be required.
>
> Best wishes
>
> Elaine
>
> ---
>
> **From:** Philip Bath [mailto:philip.bath@nottingham.ac.uk]
> **Sent:** 26 April 2009 21:17
> **To:** Godfrey, Dr Elaine
> **Subject:** Fwd: PODCAST trial: CONFIDENTIAL
>
> Dear Elaine,
>
> Not sure if you ever received this email?
>
> Philip
>
> Begin forwarded message:
>
> > **From:** Philip Bath <philip.bath@nottingham.ac.uk>
> > **Date:** 7 April 2009 23:11:17 BST
> > **To:** Elaine Godfrey <elaine.godfrey@mhra.gsi.gov.uk>
> > **Subject:** **PODCAST trial: CONFIDENTIAL**
> >
> > Dear Elaine,
> >
> > You may remember we talked a month or so ago on the telephone about the PODCAST trial (http://www.podcast-trial.org/), an academic study funded by The Stroke Association and Alzheimer's Society. PODCAST will compare 'intensive' versus 'guideline' management strategies in the prevention of cognitive decline and dementia in patients with previous stroke. The management strategies relate to:
> > 1. 'intensive' versus 'guideline' blood pressure lowering; and
> > 2. 'intensive' versus 'guideline' lipid lowering.
> > The basic design is multicentre, prospective, randomised, open-label, blinded-endpoint, controlled partial-factorial trial; no placebos will be used. Treatment will last up to 8 years.
> >
> > We consider the trial a management rather than drug trial since lifestyle advice (salt, stanols etc) in addition to drugs are used. Management algorithms will guide investigators in how to control BP and lipids to achieve targets. With respect to drug therapy, the algorithms will identify drug classes (e.g. ACE-inhibitors, beta-blockers etc) on the basis of existing drugs/classes; investigators will choose their own drug and dose as per local prescribing protocols and guidance. Although we will record the chosen drugs and doses (by class) as entered by the investigator, we do not plan on having labeling or recording batch numbers etc.
> >
> > The question is whether the trial is a CTIMP? If not, I then assume the trial is not of interest to MHRA?
> >
> > I am available on 07798 670726 for further information, and attach the draft protocol.
> >
> > All the very best for Easter,
> >
> > Philip
>
>