From: Harpal Kumar [mailto:Harpal.Kumar@cancer.org.uk]
Sent: 09 December 2015 18:19
To: Susan
Cc: Fiona Reddington; Sara Hiom
Subject: RE: breast screening age-extension trial

Dear Susan,

Thank you for your email dated 2nd November 2015, and copied below for ease of reference, regarding the breast screening age-extension trial. I apologise again for the delay in replying.

It is important to clarify that CRUK is not a funder of the trial itself and thus the questions you raise in your email below do not apply. The Principal Investigator for this trial is Julietta Patnick and the trial is supported by Public Health England and the NHS Breast Screening Programme.

CRUK does provide programme grant support to Professor Dame Valerie Beral at the University of Oxford whose team does undertake work on the trial as part of a broad range of activities related to cancer epidemiology work. However, we do not provide funding for the trial itself. The ISRCTN link which lists CRUK as a funder is incorrect.

Yours sincerely
Harpal Kumar

Harpal S Kumar

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From: Susan [mailto:sbewley@doctors.org.uk]
Sent: 02 November 2015 12:33
To: 'Harpal Kumar'
Cc: 'Les Rose'; 'lois.wilson@cancer.org.uk'
Subject: breast screening age-extension trial

Dear Harpul Kumar

I understand that CRUK is a funder of the nationwide cluster-randomised trial of extending the NHS breast screening age range in England, http://www.isrctn.com/ISRCTN33292440 a cluster RCT without explicit consent running since 2009 and which has undergone major revision in the light of the 2012 Marmot report finding of equipoise and our submissions.

Healthwatch-UK (a charity "for science and integrity in medicine") has concerns about the science and ethics – all detailed on its website starting with http://www.healthwatch-uk.org/news/44-concerns-over-age-extension-trial-of-mammography-screening-part-1.html. You will see that it took an FOI request to obtain a copy of the initial protocol v1 and there are grave scientific concerns about its credibility, especially considering the trial referred to "so-called" overdiagnosis from the start (which we last had cause to discuss in the light of the CRUK handling of the Marmot press conference).

I would be very grateful to understand CRUKs role in supporting this trial:

a) What were the CRUK review and governance processes when this trial started?
b) Would CRUK have expected such an RCT that it funded to satisfy ICH-GCP?
c) As a cofounder, how was the CRUK informed, involved with, and satisfied by, (a) the initial peer review process of protocol v1, and (b) the change of research question to protocol v3?
d) How much funding have you supplied and will continue to supply?

With best wishes

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