

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

Report to the TMG by the Data Monitoring and Ethics Committee

8th November 2011

14:00 – 15:30

Teleconference

Present

Professor Janet Darbyshire (JD) (chair)

Dr Rosalind Given-Wilson (RGW)

Professor Tom Meade FRS (TM)

Dr Gillian Reeves (GR)

Ms Jenny Rusby (JR)

In attendance for open session only

Professor Dame Valerie Beral (VB)

Kath Moser (KM)

Professor Sir Richard Peto (RP)

Report from the DMEC to the TMG following the DMEC meeting of 8th November 2011

It was agreed that the DMEC should meet annually (preferably in person rather than by teleconference), usually in October/ November to fit in with the schedule for the annual cycle for receiving screening data. It was suggested that the next meeting of the DMEC should take place as an in person meeting on the same day as the NHSBSP age extension trial management group meeting.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Committee
9th January 2013
14:00 – 15:30
Cancer Epidemiology Unit, University of Oxford**

Present

Professor Janet Darbyshire (chair)
Dr Rosalind Given-Wilson
Professor Tom Meade
Dr Gillian Reeves
Ms Jenny Rusby

In attendance for open session only

Kath Moser
Professor Sir Richard Peto
Hayley Abbiss

Report from the DMEC to the TMG following the DMEC meeting of 9th January 2013

The DMEC is encouraged by the progress to date in implementing the trial and will be very interested to see data from the trial at our next meeting, particularly on uptake of screening.

It will be very helpful to see an outline of the intended monitoring analyses before the next meeting, as discussed in the Open Session and the draft Statistical Analysis Plan although we appreciate that this will evolve over time until the database is locked for the final analysis.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

Report to the TMG by the Data Monitoring and Ethics Committee

28th January 2014

11:00 – 13:00

**Room 35, First Floor, Grosvenor Wing,
St George's Hospital, Tooting, London, SW17 0QT**

Present

Professor Janet Darbyshire (JD) (chair)

Professor Tom Meade (TM)

Ms Jenny Rusby (JR)

Kath Moser (KM) (Trial Epidemiologist)

Apologies

Dr Rosalind Given-Wilson (RGW)

Dr Gillian Reeves (GR)

In attendance for open session only

Professor Sir Richard Peto (RP) (teleconference)

Hayley Abbiss (HA)

Report from the DMEC to the TMG following the DMEC meeting of 28 January 2014

The DMEC congratulates the Trial Team and Breast Screening Units on the progress of the trial to date and was pleased to see some early data.

The DMEC was concerned to hear that the Trial Team are experiencing some difficulties in securing REC approval of the substantial amendment to the protocol. The delay in updating the trial documents is of immediate concern but the delay in beginning to plan for the linkage to other NHS records will be increasingly important as the trial progresses.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

Report to the TMG by the Data Monitoring and Ethics Committee

28th January 2015

14.30-16.00

Cancer Epidemiology Unit, University of Oxford

DMEC Open Session

Present

Professor Janet Darbyshire (JD) (chair)

Dr Rosalind Given-Wilson (RGW)

Professor Gillian Reeves (GR)

Ms Jenny Rusby (JR)

Kath Moser (KM) (Trial Epidemiologist)

Apologies

Professor Tom Meade (TM)

In attendance open session only

Professor Sir Richard Peto (RP)

Professor Dame Valerie Beral (VB)

Krys Baker (KB)

Report from the DMEC to the TMG following the DMEC meeting of 28 Jan 2015

The DMEC congratulates the Trial Team and Breast Screening Units on the continued progress of the trial and was delighted to hear that the substantial amendment finally has formal approval from the REC. The DMEC would like to reiterate that whilst it is happy to advise the Trial Team on ethical issues as these arise it does not have responsibility for the ethical approval of the trial.

The DMEC was pleased to see good progress in the conduct of the trial and the plans for linking to routine data sets. They also welcomed the appointment of the trial administrator and the team's plans to set up a website which will improve communication between the trial team and the TMG and collaborating units. They supported the plan to put the minutes of the TMG and the Report from the DMEC to the TMG on the website.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Committee
11th January 2016
Public Health England, Wellington House, London SE1 8UG**

Present

Professor Janet Darbyshire (JD) (chair)
Professor Tom Meade (TM)
Professor Gillian Reeves (GR)
Ms Jenny Rusby (JR)
Kath Moser (KM) (Trial Epidemiologist)

Apologies

Dr Rosalind Given-Wilson (RGW)

In attendance for open session only

Krys Baker (KB)
Professor Dame Valerie Beral (VB)
Professor Julietta Patnick (JP)
Professor Sir Richard Peto (RP)

Report from the DMEC to the TMG following the DMEC meeting of 11 Jan 2016

The DMEC was pleased to see that the trial was progressing well and congratulated the Trial Team and collaborating Breast Screening Units on the excellent recruitment. They were concerned to hear that there had been problems in relation to access to HES data and hoped that this would soon be resolved. They also noted the problem with provision of Patient Information Sheets at one site but were pleased that this had been resolved to the satisfaction of the REC.

The DMEC welcomed the increased communication with Collaborating Breast Units through a letter and newsletter and the establishment of a website and stressed the importance of this.

The DMEC had no concerns about the trial and plans to meet again early in 2017.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Committee
20th February 2017**

**Cancer Epidemiology Unit, CEU, NDPH, University of Oxford Richard Doll Building, Old Road
Campus, Oxford OX3 7LF**

Present

Professor Janet Darbyshire (JD) (chair)
Dr Rosalind Given-Wilson (RGW)
Professor Tom Meade (TM) (via teleconference)
Professor Gillian Reeves (GR)
Ms Jenny Rusby (JR)
Professor Sir Richard Peto (RP) (Trial Statistician)
Kath Moser (KM) (Trial Epidemiologist)
Keith Shaw (KS) (Trial Statistician)

In attendance for open session only

Krys Baker (KB)
Professor Dame Valerie Beral (VB)
Professor Julietta Patnick (JP)

Report from the DMEC to the TMG following the DMEC meeting of 20th February 2017

The DMEC would like to congratulate the Trial Team and collaborating Breast Screening Units on the progress of the trial and the substantial recruitment to date. They were pleased to hear that the problems with regard to access to HES data had been resolved and that the team was now in a position to link several key large data sets.

The DMEC noted the positive outcome of the Independent Scientific Review of the trial conducted by PHE and stressed the importance of ongoing communication with the Collaborating Breast Units whose support was crucial to the success of the trial and in particular the extension of the age groups at a time when all areas of the NHS are under increased pressure. They noted the delay to the extension to the additional two age groups and hoped that this would be resolved soon and that one or two pilots might be started in 2017

The DMEC had no concerns about the progress of the trial and plans to meet again early in 2018. They would like to thank Kath Moser for all her work on the trial and wish her well for the future.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Committee
22nd February 2018
via Teleconference**

Present

Professor Janet Darbyshire (JD) (chair)
Dr Rosalind Given-Wilson (RGW)
Professor Gillian Reeves (GR)
Professor Sir Richard Peto (RP) (Trial Statistician)
Isobel Barnes (IB) (Trial Statistician)

Apologies

Professor Tom Meade (TM)
Ms Jenny Rusby (JR)

In attendance for open session only

Professor Dame Valerie Beral (VB)
Professor Julietta Patnick (JP)
Keith Shaw (KS)
Krys Baker (KB)

Report from the DMEC to the TMG following the DMEC meeting of 22nd February 2018

The DMEC congratulates the Trial Team and collaborating Breast Screening Units on the continued successful progress of the trial. They were delighted to see the progress in accessing and linking the large datasets which provide the key data for the trial although some of these datasets are not fully up to date.

The DMEC was disappointed by the further delay to the extension to the additional two age groups and hoped to see progress before their next meeting. They commented again on the importance of ongoing communication with the collaborating Breast Screening Units as the success of the trial depends on them.

The DMEC has no concerns about the progress of the trial and plans to meet again in early 2019.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Group
25th April 2019**

The DMEC congratulates the Trial Team and collaborating Breast Screening Units on the continued progress of the trial. They were sorry to hear of the problems which the Trial Team has encountered over the past year because of the 2018 breast screening incident related to the change in the definition of the screening age range and leading to interruption in the linkage of AgeX databases to national databases (except Hospital Episode Statistics (HES) updates). This inevitably led to limitations in the analyses available to the DMEC which we hope will be resolved before our next meeting. At this stage of the trial this delay was not a major concern for the DMEC. We understand that as a result of the 2018 incident the support from PHE for the AgeX trial has increased as the Independent Parliamentary Enquiry recommended that the trial should continue until 2026 and the trial now has a further five years of funding from Cancer Research UK and MRC

The DMEC was disappointed by the further delay to the extension of screening to the additional age groups and hoped that before the next meeting the Trial Team would have had discussions with PHE and the collaborating Breast Screening Units to assess the feasibility of the age extension.

The DMEC stressed again the importance of ongoing communication with the collaborating Breast Screening Units as the success of the trial depends on them.

The DMEC plans to meet again in early 2020

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Group
31st March 2020**

The DMEC congratulates the trial team and collaborating Breast Screening Units on the continued successful progress of the trial. In particular, the considerable improvement in the data linkages has strengthened the data which the DMEC was able to review.

The DMEC has no concerns about the progress of the trial or the interim analyses and plans to meet again early in 2021 unless a need arises for an earlier meeting.

AGEX TRIAL DATA MONITORING AND ETHICS COMMITTEE (DMEC) REPORT

**Report to the TMG by the Data Monitoring and Ethics Group
15th April 2021**

The DMEC congratulates the trial team and collaborating Breast Screening Units on the continued successful progress of the trial. In particular the continued high quality and timely data linkages were noted.

The DMEC has no concerns about the progress of the trial or the interim analyses and plans to meet again early in 2022 unless a need arises for an earlier meeting.