



### Contact us

If you have a query please contact one of the team:



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# MifeMiso Trial

ISSUE 3

MARCH 2018

## MifeMiso recruitment

### surpasses 200!



Hello and welcome to the third edition of the MifeMiso newsletter! As (hopefully the last) of the snow melts and we enter Spring we're delighted to confirm that recruitment has now surpassed the 200 mark! This is an excellent achievement and wouldn't be possible without the continued hard work of research and clinical teams across our recruiting sites so we would like to express a very well deserved thank you!

We continue to remain significantly ahead of target

with January and February our highest recruiting months with 53 and 45 women randomised respectively. We would very much like to maintain this momentum in order to ensure the monthly targets are reached which will increase to 40 from July 2018 so please keep up the good work!!

Congratulations to teams at Bristol, UCLH and Coventry for winning MifeMiso recruiter of the month for December, January and February respectively! We hope you liked your MifeMiso goodies.

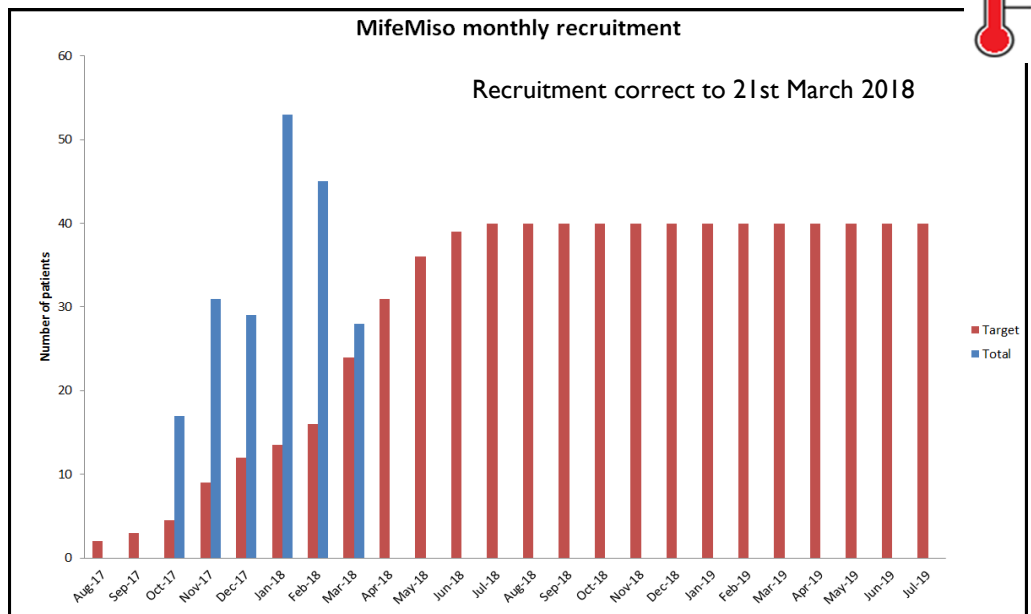
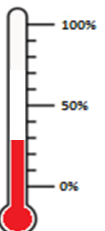
Remember your site just needs to randomise one lady for a particular month to have a chance of winning so get your randomisations in quick to be in with a chance of winning for March!

Finally, we would like to wish you all a Happy Easter and hope you have a wonderful Easter break!



29% of the way!

203 recruited/710 total target



# CRF Return Rates - can you help?

Thank you to research teams for your hard work in completing data entry and reminding women to return their completed questionnaires. CRF return rates (correct to 20th March 2018) are stated below which we would very much like to improve on.



| Form                  | Received/expected                    |
|-----------------------|--------------------------------------|
| Baseline medical data | 200 received/ 202 expected (99.0%)   |
| Baseline EQ-5D-5L     | 199 received/ 202 expected (98.5%)   |
| Day 6-7 EQ-5D-5L      | 174 received/ 196 expected (88.8%)   |
| Outcomes              | 139 received/ 164 expected* (84.8%)  |
| Day 21 EQ-5D-5L       | 124 received / 164 expected* (75.6%) |
| Satisfaction survey   | 102 received / 140 expected† (72.9%) |

\*Number expected = women at 4 weeks post-randomisation

†Number expected = women with discharge date on Outcomes form



Please note the below points to help increase return rates:

## Day 6-7 EQ-5D-5L

- ◆ If a woman attends for a scan earlier than day 6-7 and her sac has passed (therefore not requiring another scan at day 6-7) – please ensure an EQ-5D-5L is completed at the scan appointment. If it is missed please call the woman by day 6-7 to complete this over the phone
- ◆ If a woman does not attend for her scan at all please also call the woman by day 6-7 to complete this over the phone
- ◆ Alternatively if a woman does not attend for her scan and this is re-arranged for after day 6-7 please ensure an EQ-5D-5L is completed at this appointment

## Day 21 EQ-5D-5L and Satisfaction Survey

- ◆ If women do not answer to phone calls we would be grateful if you could text (if you have access to a work mobile) and email (if the woman has provided an email address)
- ◆ If feasible, offer women the option of returning at day 21 to conduct their pregnancy test and complete the questionnaires

*“It is very pleasing to see that participant and site recruitment is going so well ”*

## Feedback from NIHR

We received a very positive letter from the funder in response to the progress report submitted in February. The Senior Research Manager reported “It is very pleasing to see that participant and site recruitment is going so well”. This is very encouraging and is down to the dedication of all our sites. Keep up the good work!





## Substantial amendment 3



The documentation for substantial amendment 3 was submitted to REC, HRA and MHRA on 8th March 2018 following approval from the BCTU QA team and the funder. We have since received amendment acknowledgements from REC and MHRA along with the HRA categorisation email which has confirmed the amendment is category A. We have supplied sites (including members of the research team, pharmacy team and R&D) with the amendment documentation for review. As stated by email, sites have 35 calendar days to review the amendment from the date of notification therefore if your site does not raise an objection to the amendment by **25th April 2018** we will assume the amendment may be implemented at your site once all regulatory approvals are in place. Once approvals have been issued from REC, HRA and MHRA these will be forwarded to sites.

We will send hard copies of the amendment documentation to the main contact in the research team at each site once approvals have been obtained. Please ensure this is filed in the site file and relevant documentation is filed in the pharmacy folder.

When updating the Satisfaction Survey we would be grateful if research teams could keep page 1 which includes the validated CSQ-8 questionnaire and only replace page 2 of the questionnaire which contains additional instructions for the woman to scan and email her questionnaire to the MifeMiso NHS.net account or complete the questionnaire electronically (as well as having the option to post). This is because we are required to pay per copy for the CSQ-8 questionnaire so please ensure you use copies you already have!

Please also let the trial team know if you would like to have laminated copies of either of the clinic trial posters which have been adapted (one poster with the wording 'Have you been diagnosed with a missed miscarriage?' removed and the other including the term 'delayed' as well as 'missed').

## Reminders



### \* Data queries

Please ensure that you are regularly checking the 'monitoring' tab on the MifeMiso database for any queries raised. Once you have checked your queries please save your response so this can be checked by the MifeMiso team. If you have any queries about this, please contact a member of the team

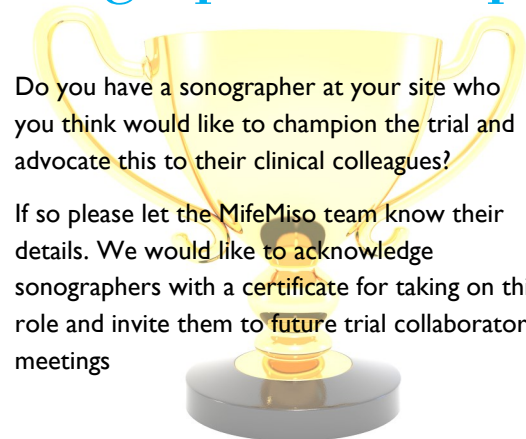
### \* MifeMiso Meet Up - 29th May 2018

The next MifeMiso Meet up teleconference will be on Tuesday 29th May 2018, 11.30am - 12.30pm. If you haven't already please respond to the calendar invite to confirm your availability. We look forward to speaking with you

### \* Site payments

Don't forget to invoice for your site payments. Invoices should be addressed to Leanne Beeson and submitted on a quarterly basis. Payments include £150 for site file maintenance and archiving, £275 for pharmaceutical receipt and dispensing of IMP and £150 per patient recruited. In addition, wave 1 sites can invoice for 20% FTE research nurse support

## Sonographer champion



Do you have a sonographer at your site who you think would like to champion the trial and advocate this to their clinical colleagues?

If so please let the MifeMiso team know their details. We would like to acknowledge sonographers with a certificate for taking on this role and invite them to future trial collaborators meetings

## Parity-Data entry

Important Notice

Please take extra care to ensure that during randomisation the woman's parity has been entered correctly. We are aware of some inconsistencies between the response given to 'Is the woman nulliparous?' and the previous pregnancies recorded on the Baseline Medical Data form which we will query with sites

# Collaborators meeting - Save the date!

We have provisionally scheduled a collaborators meeting for **Tuesday 11th September 2018** to be held at Birmingham Women's Hospital. Lunch and travel expenses will be provided. Invitees will include research staff involved in MifeMiso including P.Is, Obstetricians, Gynaecologists, junior doctors, research nurses/midwives and sonographers. Please hold this date in your diaries and we will be in touch to confirm details nearer the time

**Save  
the  
Date**



**WELCOME**

**New sites**

We would like to welcome Epsom and St Helier Hospitals and Burnley General Hospital who will be opening to recruitment soon! This will take the total number of open hospitals to 27 across 21 trusts. We wish them the best of luck with recruitment!

## Reminder - BCTU Easter Closure



Please note that BCTU will be closed from **5pm on Thursday 29th March 2018 and will re-open at 9am on Thursday 5th April 2018**. During this period the BCTU telephone randomisation service will be unavailable however the online randomisation system ([www.medscinet.net/mifemiso](http://www.medscinet.net/mifemiso)) will continue to be available 24/7.

If you need to report an SAE during this period please continue to email reports to the MifeMiso NHS.net account ([bwh-tr.mifemiso@nhs.net](mailto:bwh-tr.mifemiso@nhs.net)) or fax to 0121 415 9136

- 1. Missed Miscarriage**
- 2. Medical Management**
- 3. Think MifeMiso!**



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[🐦: @mifemiso\\_trial](https://twitter.com/mifemiso_trial)