



MONARCH STUDY

MONITORING AMD AT HOME

NEWSLETTER

ISSUE:2 Summer 2018

MONARCH Update

Hello MONARCH Teams across the UK!



Since the last newsletter we have obtained all necessary approvals and have opened to recruitment! Thanks for your patience whilst the equipment was set-up and good luck recruiting your first patients!

Dr Ruth Hogg, Co-Chief Investigator

Message from the study management team

Thanks to **James Paget** for the brilliant suggestion of a clinic poster aimed at potential patients— a substantial amendment to approve this is being prepared, we'll keep you updated on timelines for this!

Well done to **Belfast** for your speedy SL1 data entry for approached patients! 55 patients approached already - fantastic work!

Please keep **queries and suggestions coming** and thanks for your patience as we iron out "teething" issues in the database!

TIMELINE

FEBRUARY 2018

- REC ethical approval.

MARCH-MAY 2018

- Site Initiation Visits to MONARCH sites in Belfast, James Paget and Liverpool.

JUNE 2018

- Site Initiation Visits to MONARCH site in Southampton.

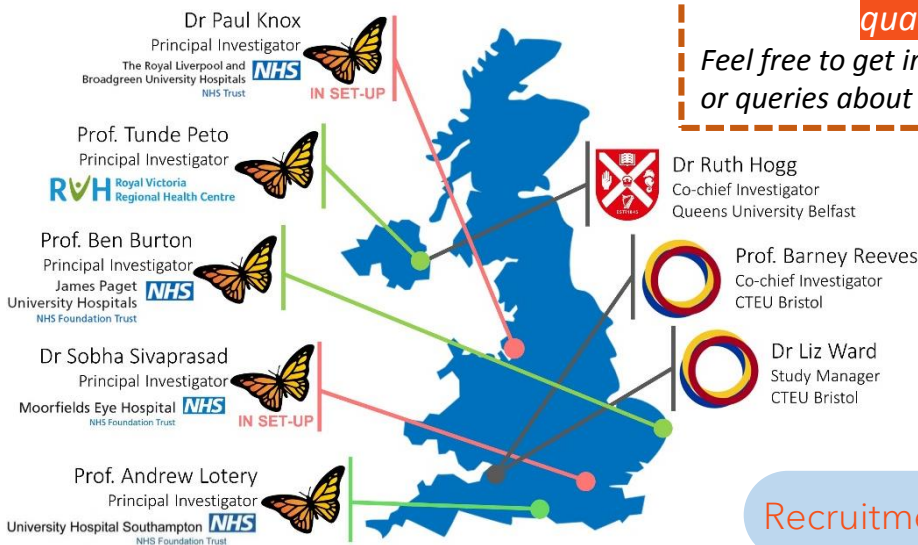
JULY 2018

- Site Initiation Visits to MONARCH site in Moorfields.
- HRA approval received.
- Study equipment preparations finalised.
- Belfast site opened!

AUGUST 2018

- Southampton and James Paget sites opened.

The MONARCH Teams



Message from Dr Charlene Treanor-qualitative researcher

Feel free to get in touch if you have any questions or queries about the qualitative research

Progress figures

as of 16/Aug/2018:

3/5 Sites open

55 Total approached

0 Total recruited

Recruitment Target: **400**



MONARCH Study

Clinical Trials & Evaluation Unit
Bristol Royal Infirmary,
Bristol, BS2 8HW



**CTEU
Bristol**



**QUEEN'S
UNIVERSITY
BELFAST**

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NHS
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Health Research

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.



Tips for new sites

SCREENING

An SL1 form should be completed for each patient approached for the MONARCH study.

STAFF

Remember to update us on all staff changes within the MONARCH team to ensure the study management system is kept up to date.

POSITIVITY

Your attitude towards the tests will influence the participants attitude. Please do try to be positive and enthusiastic about the tests!

DATABASE

When entering a new patient into the database, search the patient ID without the dash (e.g. BEL0013 instead of BEL-0013) and an option will then appear to create a new patient with that ID.

EQUIPMENT

Please familiarise yourself with the home monitoring tests (how to use them, how to train patients, how to activate them) before training your first patient.


RECRUITMENT

Patients can be recruited with inactive or active AMD. However, please wait until the clinic review after an injection cycle is completed before the patient training session.


The Tests




MyVisionTrack – the ‘bumpy circles’ test
Tap on the odd one out



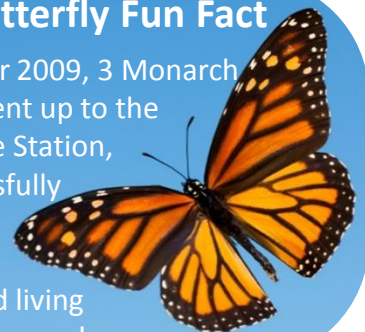
MultiBit Test – the ‘numbers’ test
Say the numbers that appear



The KeepSight Journal
Complete the puzzle & tests

Monarch Butterfly Fun Fact

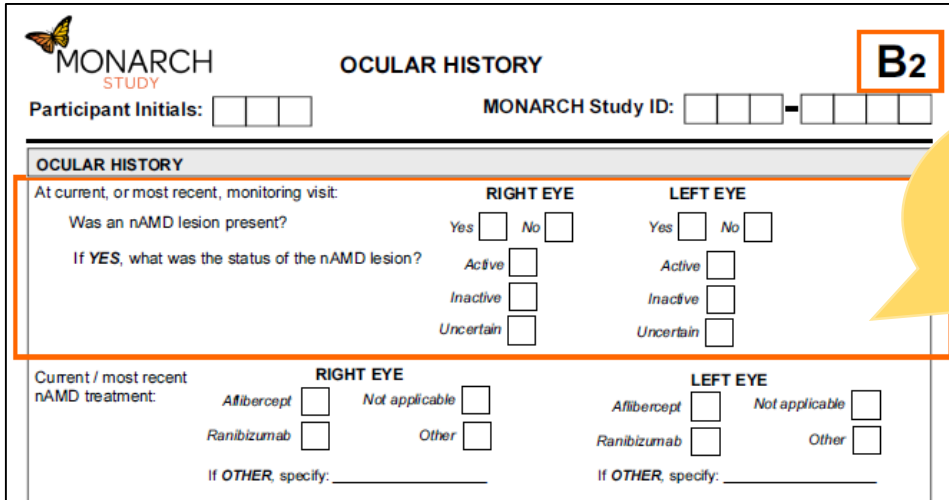
On 16th November 2009, 3 Monarch caterpillars were sent up to the International Space Station, where they successfully pupated, emerging on the 3rd and 4th of December and living for a week in space!



Upcoming CRF changes

B2: new question on baseline nAMD activity status: was a lesion present and if yes, what status?

F1: treatment information required each time a management decision is made, including the first time F1 is completed



CRF changes:
V5.0 will be rolled out to database around **mid-Oct**

*B2 baseline activity status data will be required for **all participants screened from the start of the study** so please note **nAMD activity status at baseline for each eye** on your paper CRF for each patient to save having to look this up retrospectively for participants in future.*

Forthcoming University Closure Days!:

The study management office and technical support line will be **closed Monday 27th August and Tuesday 28th August**. You should continue to approach and recruit participants but we will not be available for queries. We will be back in the office to answer calls and queries Wednesday 29th August.

Study Contact Details

Study management team (Liz Ward & Robin Wickens):

✉ MONARCH-study@bristol.ac.uk

☎ 0117 342 2526

Qualitative team (Dr Charlene Treanor)

☎ 02890 971606

✉ monarch-qualitative@qub.ac.uk

MONARCH Technical Support Line

☎ 07530370171

Mon-Fri: 9:00-17:00

CLOSED Mon 27th & Tues 28th Aug