

## Achievements

Thank you to those sites which registered patients in March & April:

- Royal Cornwall Hospital NHS Trust
- Royal Hampshire County Hospital
- New Cross Hospital, The Royal Wolverhampton NHS Trust
- Colchester General Hospital

Welcome to  
**St James University Hospital, The Leeds Teaching Hospitals NHS Trust**  
**who opened to recruitment in March**  
&  
**Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust**  
**who opened to recruitment in April**

## Recruitment Update

43 Participants Registered  
26 Participants Randomised  
23 Sites Open to Recruitment

## Meet us at the BSH Conference



## *A message from the CI*

Many thanks for your continued hard work and engagement with the REPAIR-MDS study, together with that of your research colleagues.

Both my Co-CI Manoj Raghavan and I will be attending the BSH conference in Liverpool on 28-30th April 2024.

If you are also attending BSH, we'd be delighted to answer any questions or queries you may have regarding REPAIR-MDS, as well as take the opportunity to share our plans for the expansion of the study too.

**Dr Stephen Jenkins**  
**Clinical CI REPAIR-MDS**

## Reminder - Patient dose interruptions

Just a reminder, if the patient had their dose interrupted, we still require the following:



**A scanned copy of the redacted prescriptions to be sent securely via email to us**



**The Dose Monitoring & Response Evaluation Forms to be entered in the Trial database**

Please refer to the CRF Clinic recordings available on the REPAIR-MDS website [here](#) for further guidance on data entry.

The image shows two overlapping CRF forms. The top form is the 'REPAIR MDS Dose Monitoring Form' (Form 25), version 1.1 1004c2021. It includes fields for 'Participant Trial Number' and 'Site Code', and a 'Time point: Week' field. Below these are instructions for patients who are not deviating from their primary dose escalation and for those who are re-escalating, discontinuing, or interrupting their primary escalation. Section 1 is titled '1. PRESCRIBING' and includes a sub-section '1.1 Dose prescribed at last visit:'. The bottom form is the 'REPAIR MDS Response Evaluation Form - Week 0' (Form 6), version 3.0 130c12023. It includes fields for 'Participant Trial Number' and 'Site Code'. Section 0 is titled '0. TREATMENT DETAILS' and includes fields for '0.1 Number of weeks from Randomisation', '0.2 Treatment stage', and '0.3 Treatment Week'. Section 1 is titled '1. PARTICIPANT OBSERVATIONS' and includes a field for '1.1 ECG status'. Below this is a table for vital signs: Blood Pressure (mm/Hg), Pulse (bpm), Temperature (°C), O<sub>2</sub> Saturation (%), and Date of Observations. The table has columns for values and units.

## Sodium Valproate Dispensing MHRA Guidance

In light of the recent guidance on dispensing of Sodium Valproate issued by the MHRA, we have submitted an amendment to the protocol to exclude anyone under the age of 55 years and males planning to father a child from the trial.

**Please be mindful of this if you are planning or are currently screening any patients that would fit this criteria.**

## Extension to Recruitment

The current recruitment end date is 30th June 2024.

**We are happy to announce that participant recruitment will be extended to June 2025.**

The extension to the recruitment period will not have any additional resource implications for participating organisations and is still within the current grant funding period.

We are in the process of submitting an amendment to formalise this change. We will circulate all relevant regulatory approvals once received.

# Recruitment Update



Well done and thank you to our top recruiting sites!

	REPAIR-MDS Site	Date Opened to Recruitment	Participants Registered	Participants Randomised
<b>1</b>	Russell's Hall Hospital	21-Dec-21	5	3
<b>2</b>	Royal Cornwall Hospital NHS Trust	02-Sep-22	4 <b>NEW</b>	3
<b>3</b>	Kent and Canterbury Hospital	21-Apr-22	4	2
	University Hospital College London	11-Mar-22	3	2
	Good Hope Hospital	12-Oct-22	3	2
	King's College Hospital NHS Foundation Trust	12-Apr-22	3	2
	Nottingham City Hospital	31-Jul-23	2	2
	Castle Hill Hospital	10-May-22	2	2
	University Hospitals of Leicester NHS Trust	08-Dec-22	3	1
	Royal Hampshire County Hospital	31-May-23	3 <b>NEW</b>	1
	Royal Gwent Hospital	30-Jun-22	2	1
	James Paget Hospital	04-Jul-23	2	1
	Aberdeen Royal Infirmary	29-Mar-22	2	1
	Heartlands Hospital	12-Oct-22	1	1
	University Hospitals Dorset NHS FT	17-Jul-23	1	1
	Basingstoke and North Hampshire Hospital	05-Jun-23	1	1
	Colchester General Hospital	11-Aug-22	1	0
	New Cross Hospital	08-Feb-24	1 <b>NEW</b>	0
	South Tees Hospitals NHS Foundation Trust	04-Jan-23	0	0
	Broomfield Hospital	22-Nov-22	0	0
	Rotherham Hospital	05-Oct-23	0	0
	St James University Hospital	26-Mar-24	0	0
	Queen Elizabeth Hospital	15-Apr-24	0	0
	<b>TOTAL</b>		<b>43</b>	<b>26</b>