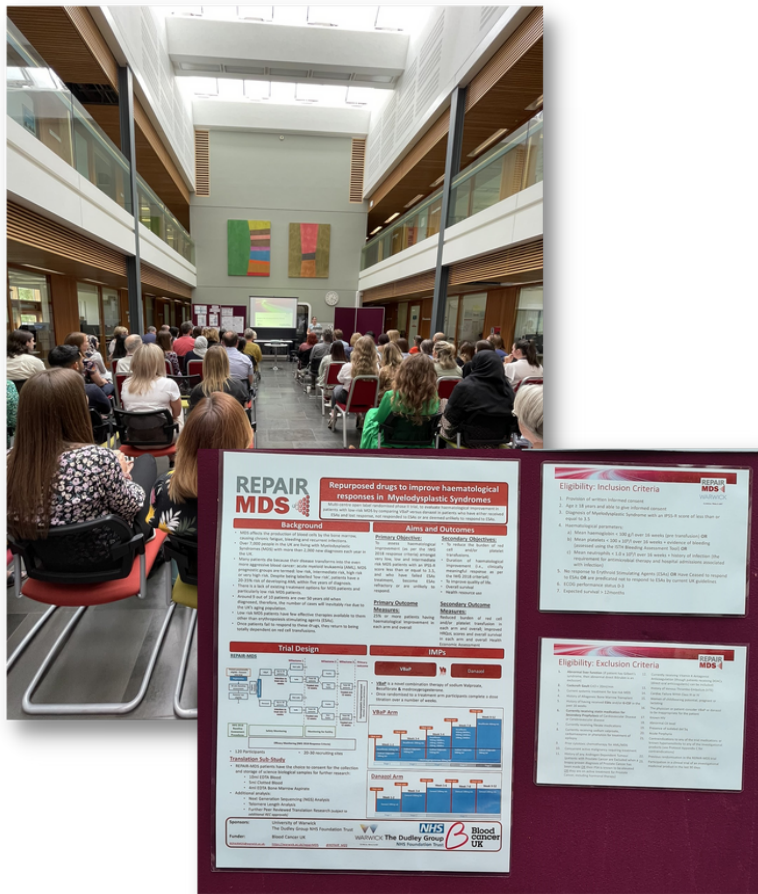


REPAIR-MDS Newsletter

May 2022, Issue 03

Clinical Trials Day

REPAIR-MDS team celebrated Clinical Trials Day on 20th May by attending Warwick Clinical Trials Unit Poster Showcase event.



May Achievements

Kings College London Hospital has registered their 1st patient! We now have 4 participants registered!

Castle Hill Hospital is open to recruitment as of this month! Welcome onboard!

A big thank you to **Russell's Hall Hospital** for the 100% CRF completion rate. Keep up the good work!

REPAIR MDS

Screening logs

Screening data is really important for us to check our inclusion and exclusion criteria is correct and help us identify any barriers to recruitment as soon as possible!

Please include **all MDS patients** screened in your monthly screening log – including those patients:

- deemed ineligible at pre-screening
- have been informally reviewed
- attended your MDS clinic
- patients you have approached and are still considering the trial – you can update us when they have made their decision

Screening numbers should be sequential and carry over from month to month – this helps us track patients progress through the screening process

Don't hesitate to get in touch if you have any queries or require any support with screening - We are always happy to help!

We have coded the most common reasons for patients to not be eligible or not wanting to enter the trial to streamline the process – You only need to note down the reason code listed on the last page of the screening log

Repair-MDS Screening Log

Site: _____ Screening Period (MMM/YYYY): _____ Screening Clinician: _____

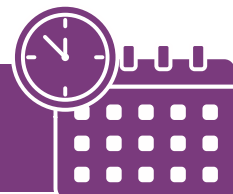
Screening no. (e.g. RMD01)	Date Pre-Screened (dd/mm/yyyy)	Initials	Age (yr)	Gender (F/M)	Ethnicity ¹	Potentially eligible? (Y/N)	Is patient willing to take part? (Y/N)	Reason patient is ineligible or unwilling ²	Patient registered? (Y/N)	Trial No. (if registered)	Patient confirmed as fully eligible ³ (Y/N)	Reason patient not fully eligible ⁴	Date patient randomised (dd/mm/yyyy)



Repair-MDS Screening Log Ethnicity, Ineligible and Unwilling Codes

Ethnicity codes	Reason codes if patient not eligible	Reason codes if patient not willing:
White A. A. English, Welsh, Scottish, Northern Irish or British B. Irish C. Gypsy or Irish Traveller D. Any other White background Mixed or Multiple ethnic groups E. White and Black Caribbean F. White and Black African G. White and Asian H. Any other Mixed or Multiple ethnic background Asian or Asian British I. Indian J. Pakistani K. Bangladeshi L. Chinese M. Any other Asian background Black, African, Caribbean or Black British N. African O. Caribbean P. Any other Black, African or Caribbean background Other ethnic group Q. Arab R. Any other ethnic group	1. Eligible for ESA (erythropoietin) 2. Diagnosis not definitively MDS 3. IPSS high, very high risk or AML 4. Women of childbearing potential 5. ECOG status >3 6. Poor liver function defined as: ALT/AlkPhos > 3x ULN or Bilirubin > 3x ULN (unless due to Gilberts Disease) 7. Cockcroft Gault CrCl < 20ml/min 8. Current systemic treatment for low risk MDS 9. History of Allogeneic Bone Marrow Transplant 10. History of having received ESA and/or G-CSF in the past 16 weeks 11. Currently receiving statin medications for primary prophylaxis – patient/clinician elected to continue with statin medications 12. Currently receiving statin medications for secondary prophylaxis 13. Currently receiving fibrate medications 14. Prior investigational product for MDS 15. Prior cytotoxic chemotherapy for AML/MDS 16. Concurrent active malignancy requiring treatment 17. Currently receiving Vitamin K Antagonist Anticoagulation (though patients receiving DOACs can be included) 18. History of Venous Thrombo-Embolism (VTE) 19. Cardiac Failure NYHA Class III or IV 20. Known hypersensitivity to any of the investigational products 21. Pregnancy or lactating 22. The physician or patient consider VISA® or Danao® to be inappropriate for the patient 23. Known HIV 24. CK level > than 2.5 x ULN 25. Presence of isolated del 5q 26. Acute Porphyria 27. Prognosis expected to be <12 months for any reason 28. Contraindications to trial medication (e.g. Lapp lactase deficiency) 29. Previous randomisation in the REPAIR-MDS trial. 30. Participation in a clinical trial of an investigational medicinal product in the last 90 days 31. Other, please specify	32. No reason given 33. Wanted alternative treatment 34. Did not want to wait for treatment allocation 35. Did not want to be part of a research study 36. Unable to take part in trial processes

Reminder - Bank Holiday Arrangements



A friendly reminder please do not plan to take or send any **Translational Research Samples to the Central Immunology Service** during the Bank Holiday!

Emergency Randomisation Line & Central Trial Team

Unavailable from 17:00 Wednesday 1st June
Will reopen 09:00 Monday 6th June

Central Immunology Service

Please do **NOT** take or send any samples during the Bank Holiday