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NEWSLETTER ISSUE #11 – October 2024

# REDUCe2

Palliative Long-term Abdominal Drains Versus Repeated Drainage in Untreatable Ascites Due to Advanced Cirrhosis: A Randomised Controlled Trial

# **RECRUITMENT UPDATE (as of 31st October 2024)**

A total of **135** participants have now been randomised, which equates to 44% of the overall target.

Keep up the fantastic work!



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# SITE NEWS August, September & October



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# **REDUCe2 COMMUNICATION WORKSHOPS**

The next two facilitator-led 1-day communication courses with interactive, didactic presentations, group exercises & discussions have been arranged in:

**Edinburgh** – The George InterContinental Hotel on Monday 3<sup>rd</sup> March 2025





**Birmingham** – Hyatt Regency Hotel on Tuesday 4<sup>th</sup> March 2025

Only 2 spaces left!

Workshops are suitable for any REDUCe2 core multidisciplinary team member and attract CPD points.

Attendance is **FREE** with refreshments and lunch provided.

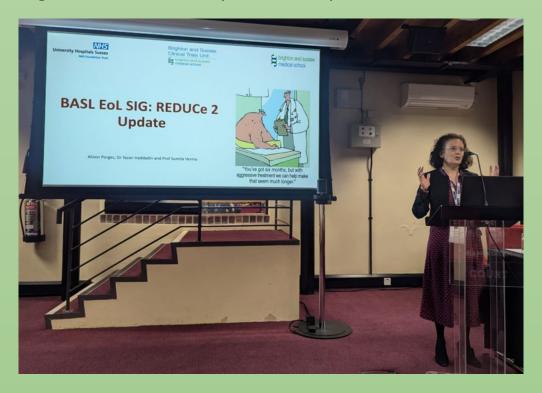
Sites can claim back up to £100 travel expenses for 2 participants.

If you're interested, please email Rachel or Helena at shorec-reduce2@sussex.ac.uk



## **Study Team news**

The BASL End of Life Special Interest Group (EoL SIG) meeting was held on Thursday 7<sup>th</sup> November in Birmingham. It was great to see some of you there in person.



Some important key points from presentation:

- Most SARs are related to leakage and occur in first 2-4 weeks so needs close collaboration with community teams. Early detection avoids hospitalisations
- Recruitment: we need 8 per month and there are 4 months when we need 11
- Please ensure SFLDQoL is completed first and check that all questions are answered



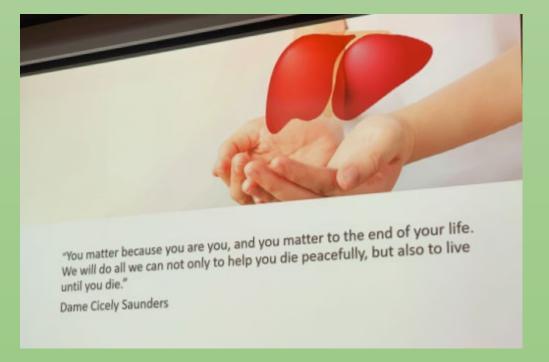




### **Study Team news**

Some more important key points from presentation:

- Proxy Scores are when the researcher / caregiver completes questionnaires on behalf of research participant and <u>NOT</u> when researcher / caregiver enters responses on behalf of participant
- EoL does not equate to withdrawing a research participant:
  - they can stay in trial if patient / caregiver willing and death not imminent
  - Retention is crucial to enable robust statistical analysis
  - Please identify the caregiver at screening





# Winners of the Hamper .....

Staff at Hull University Teaching Hospitals NHS Trust enjoying their hamper for the 100<sup>th</sup> patient to be randomised!



From left to right: Ani Kingsbury, Kim Dearnley and Julie Willcox.

# Who will win the next hamper?

We will be having a draw for those sites who randomise participant number 151 – 155.

..... Watch this space.

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# Meet the Team ..... Gina Richards – Brighton & Sussex Clinical Trial Unit



After completing a BSc Hons in Biochemistry with Physiology, Gina has spent over twenty years in the pharmaceutical manufacturing industry. After several years in the laboratory, she moved into Quality Assurance and became a specialist in computerised systems validation, and data integrity compliance, ensuring inspection ready status to MHRA standards.

Gina joined the CTU in 2024 as a data manager and uses her QA background to assist the data team in overseeing the review of data for accuracy and completeness, managing discrepancies, and data cleaning and extraction. She provides support for data entry users and the wider clinical trial team to ensure high quality data is captured to support study outcomes.

email - G.Richards@bsms.ac.uk

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# **Top Tips & FAQs**

# Ascitic fluid colours on LTAD diary vs MACRO

Blood stained	Cloudy yellow	Clear straw
i Jan		

**Diary:** 

Colour of fluid 1: blood stained 2: cloudy 3: clear

#### MACRO:

- 3. Haemorrhagic
- 2. Yellow or turbid
- 1. Clear or Straw-colour

## **Modified AHCR Questionnaires**

Should be completed every 2 weeks from Baseline even if there is no caregiver.

Where there is **no caregiver** patient to complete:

Section 1: Health and Social Care Visits / Appointments Inside the Home

- Section 2: Healthcare Visits / Appointments / Stays Outside the Home
- Section 3: New Supplies and Equipment (Weeks 2 onwards only)

Section 5: Participant Symptom / Functional Assessment (*caregiver or participant*) Section 7: Out-of-pocket Expenditures

#### Caregiver only to complete:

Section 4: Caregiving Section 6: Caregiver's Burden Scale In End-of-life Care Section 8: Caregiver Views about Healthcare and Social Services Received

# Short-Form Liver Disease Quality of Life Questionnaires

This is our Primary Outcome measure soi please double check that **all questions** have been answered in each section\* before you leave the patient.

\*questions 18-21 may be left blank

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#### **KEY CONTACTS**

#### **General study queries & Sealed Envelope password resets:**

Alison Porges (Trial Manager) <u>reduce2@bsms.ac.uk</u> Tel: 07721 860469 Dr Yaz Haddadin (Clinical Research Fellow): <u>yazan.haddadin@nhs.net</u> Tel: 07881 326775

#### eCRF queries or password resets:

Gina Richards (Data Manager): <u>G.Richards@bsms.ac.uk</u> or Debbie Lambert (Database Manager): <u>D.Lambert@bsms.ac.uk</u>

### Database for SFLDQoL & CRRS Questionnaires & Interviews:

SHORE-C Team: <u>shorec-reduce2@sussex.ac.uk</u> Tel: 01273 873019

#### Additional blood kits:

Dominika Wlazly: <u>dominika.wlazly@nhs.net</u> or <u>uhsussex.crf.lab@nhs.net</u>

#### Additional Rocket Medical LTAD Insertion Kits & Drainage Bags / Bottles:

Customer Services: customerservices@RcoketMedical.com

# Additional BD (PeritX) LTAD Insertion Kits & Drainage Bottles:

Contact your local BD rep



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# Next Newsletter will be February 2025