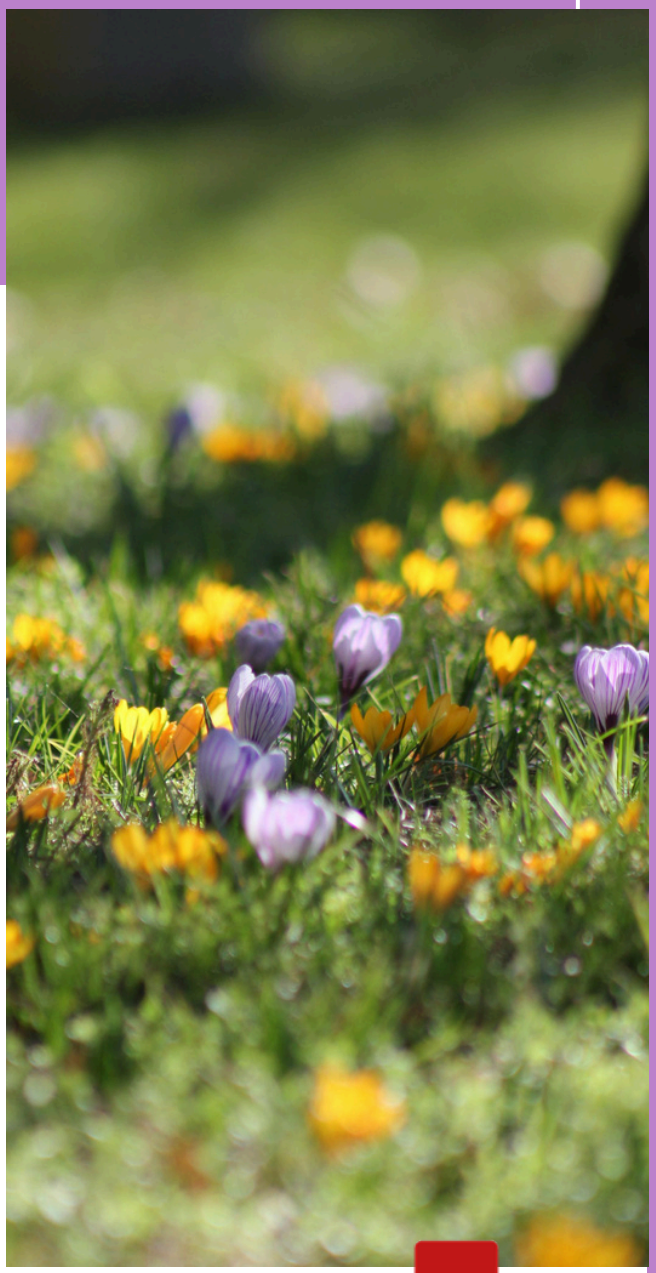
APR 2026 | NEWSLETTER 4

REACT-AVB NEWSLETTER

Randomised controlled trial of EArly transjugular intrahepatiC porTosystemic stent-shunt in Acute Variceal Bleeding



In This Newsletter...

REACT-AVB Website / Bluesky / X

A message from CI, Professor Dhiraj Tripathi & Co-CI, Dr David Patch

Dear Colleagues,

On behalf of the REACT-AVB Trial Management Group (TMG), we would like to welcome you to the fourth REACT-AVB newsletter. We are very grateful to all collaborators for their contributions. Thanks to your tireless efforts, we are approaching 100 participants, which is a major milestone. Indeed, once we pass 132 participants, REACT-AVB will be the largest ever randomised controlled trial of early or pre-emptive TIPSS in acute variceal bleeding.

REACT-AVB has completed two years of recruitment. To date, there are 26 open sites, with others in set-up. We are aiming to open 30 sites. 94 participants have been recruited so far. Recruitment has gathered pace in the last few months, and we are well on track to meet our recruitment target of 294 participants over the remaining two years of recruitment.

We offered several one-to-one meetings with site PIs and these were very constructive. Later in the newsletter, we present key points raised at these meetings. We hope to continue to offer such meetings on a regular basis.

I am delighted to inform you that recent trial oversight meetings went very well. The Trial Steering Committee Chair was highly complimentary of the running of the trial and the efforts of the trials unit and collaborators.

As you are aware, protocol changes have increased the TIPSS time window from 4 days to 5 days. This has received much approval from collaborators, and we hope it will enhance recruitment.

REACT-AVB continues to benefit from excellent engagement with the Associate PI Scheme, with 21 aPIs registered so far, and 8 have completed their programme.

We continue to offer regular virtual Q&A sessions, which sites are required to attend after reviewing the SIV slides. This is an essential step before sponsor greenlight to open your site. We are also reviewing the monthly drop-in sessions to ensure we make the most efficient use of the time.

We will keep you updated on progress with regular newsletters. In the meantime, please do not hesitate to contact us or other members of the REACT-AVB TMG if you have any queries.

Best Wishes,

Dhiraj & David

Site Update

26 sites (18 Hub sites and 8 Spoke sites) are currently open to recruitment, with further sites in set-up. A huge thank you to all of our colleagues for your hard work in making this happen!

Site	Hub/Spoke
Queen Elizabeth Hospital (Birmingham)	Hub
The Royal Free Hospital	Hub
John Radcliffe Hospital	Hub
Queen's Medical Centre	Hub
Royal Infirmary of Edinburgh	Hub
Whittington Hospital	Spoke
Derriford Hospital	Hub
Glasgow Royal Infirmary	Hub
Queen Elizabeth University Hospital (Glasgow)	Hub
Norfolk & Norwich University Hospital	Hub
Good Hope Hospital	Spoke
Northern General Hospital	Hub
Heartlands Hospital	Spoke
Southmead Hospital	Hub
Gloucestershire Hospitals NHS FT	Spoke
Queen Alexandra Hospital	Hub
New Cross Hospital	Spoke
Aintree Hospital	Hub
Northwick Park Hospital	Spoke
Manchester Royal Infirmary	Hub
Royal Liverpool University Hospital	Hub
Royal Cornwall Hospital	Spoke
St. Thomas' Hospital	Spoke
Freeman Hospital	Hub
University Hospital of Wales	Hub
King's College Hospital	Hub

Recruitment Update

94 participants have been randomised into the trial! Thank you to all open sites for your continued efforts in finding suitable patients to recruit.

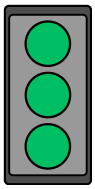
Participant recruitment by site

Site	Total number recruited
The Royal Free Hospital	26
Queen Elizabeth Hospital (Birmingham)	9
Southmead Hospital	7
John Radcliffe Hospital	7
Whittington Hospital	6
Northwick Park Hospital	6
Glasgow Royal Infirmary	5
Queen's Medical Centre	4
Queen Elizabeth University Hospital (Glasgow)	4
Gloucestershire Hospitals NHS FT	4
Royal Infirmary of Edinburgh	3
Heartlands Hospital	3
Derriford Hospital	2
Good Hope Hospital	2
Queen Alexandra Hospital	2
Manchester Royal Infirmary	2
Royal Cornwall Hospital	1
St. Thomas' Hospital	1
Norfolk & Norwich University Hospital	0
Northern General Hospital	0
New Cross Hospital	0
Aintree Hospital	0
Royal Liverpool University Hospital	0
Freeman Hospital	0
University Hospital of Wales	0
King's College Hospital	0

Site Feedback Summary

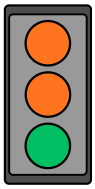
Thank you to all PIs who engaged with the 1:1 meetings offered by the Trials Team to discuss trial **successes**, **challenges** and **support available** to sites. Your feedback was extremely valuable and the key discussion points are shared below.

SITE A



"Our team regularly **engages with registrars and the radiology department**, and we **discuss the trial and eligibility criteria** often. **Posters** are displayed across staff areas. The trial is discussed at monthly rotation meetings, and the PI has delivered several **talks promoting the trial**."

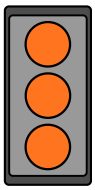
SITE B



"Our team is **engaged** and supportive of the trial. We have **strong communication between staff**. We are aware **eligible patients are being missed**. We **need more sub-investigators** with knowledge of the condition. The PI is working to add more staff to the delegation log."

BCTU Response: Encourage staff to consider becoming an aPI. The trial is registered to the aPI scheme, which benefits the PI and supports workload.

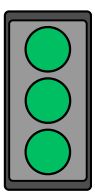
SITE C



"We only approach patients when we feel confident TIPSS can be performed immediately. This means **eligible patients may be missed**, including those who might receive SoC instead. There is **concern about meeting the 5-day TIPSS window**."

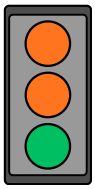
BCTU Response: All eligible patients should be screened and approached. If, after randomisation, TIPSS cannot be performed within 5 days for reasons outside the site's control, this is acceptable. This is a pragmatic study- capturing real world barriers is important. Sites are encouraged to attend the REACT-AVB monthly open site sessions for ongoing support.

SITE D



"There is excellent **communication across all departments**- from A&E through to Endoscopy and Radiology. Strong coordination ensures **timely identification and approach of potential patients**. Screening and recruitment have been very strong. Having an **aPI** has been a major benefit."

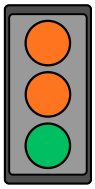
SITE E



"Having an **aPI** on board is great. They are very **engaged** and continue to **promote the trial** and support our Research Nurses. Our biggest challenge is that **A&E and the Gastroenterology team need to remember to refer patients**. Some **potential patients have been missed due to late or absent notifications**."

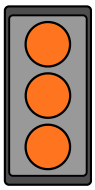
BCTU Response: Consider putting posters up to remind other departments and/or hold cross-department meetings.

SITE F



"**Communication is very strong** amongst the team. Screening and recruitment have been good, and **patients are approached in a timely manner**. The team is very engaged. We have **staff shortages**, which has impacted CRFs and DCFs. The aPI is supporting the backlog of outstanding documents."

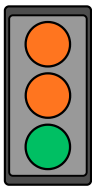
SITE G



"We are **reluctant to randomise older patients even if they meet the criteria**. **IR capacity is limited**. We have an excellent salvage TIPSS service but is stretched for trial activity. The PI does not want to overburden IR staff. Two new IR staff are being trained to support the trial."

BCTU Response: If patients meet the eligibility criteria and are clinically suitable, they should be randomised.

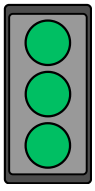
SITE H



"We have a **good set of IR staff** who can perform TIPSS. **When the PI was off, potential patients were missed. Other registrars and sub-investigators were not on the delegation log to support** the trial."

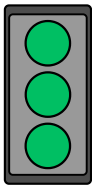
BCTU Response: Promote the trial at IR meetings and consider staff joining the aPI scheme. Consider adding more staff to the delegation log to ensure cover of trial-related activities to avoid potential patients being missed.

SITE I



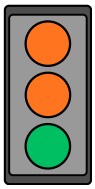
"We see a lot of ulcer bleeds in A&E. **Strong team set-up with minimal missed patients**. **Good communication with IR**."

SITE J



"We have **good communication with other departments** so are not missing any potential patients."

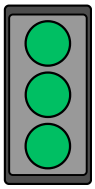
SITE K



"The **Sub-I is heavily engaged** and attends weekly Hepatology meetings to **promote the trial**. The PI feels **reluctant to randomise when Child Pugh, MELD or bilirubin are high**, even if criteria are met. There is also **concern about meeting the 5-day TIPSS window due to bed availability**."

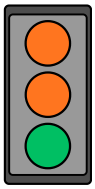
BCTU Response: If patients meet criteria and are clinically suitable, they should be randomised. We have a safety oversight committee who monitors safety closely. If, after randomisation, TIPSS cannot be performed within 5 days for logistical reasons outside site control, this is acceptable. Reasons will be captured on the Discharge Form. If in doubt or if you wish to discuss a patient, staff can reach out to the CI and co-CI directly.

SITE L



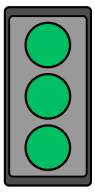
"We have a **good team set-up**."

SITE M



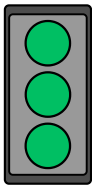
"Research Nurses **communicate regularly** with ward consultants and the Research Team. The **trial is well-advertised** and there is **strong variceal surveillance**. However, we are not seeing many variceal bleeders in A&E. There has also been a **shortage in the anaesthetics team**, there has been long term sickness so other patients who require this service are being prioritised over the TIPSS procedure."

SITE N



"We are confident that we are not missing any potential patients. **Communication across the ED, IR and Research Team has been excellent**, contributing to high morale and **strong engagement**. Clear **communication pathways are well established**, and the **Trials Unit has provided outstanding support**- consistently quick to respond and highly supportive of site staff queries."

SITE O



"We have a **good set-up with the IR team**. Excellent **aPI involvement**."

Reminders & Housekeeping

100th Patient Prize Draw

We are delighted to share that we are fast approaching a major milestone in the trial– the enrolment of our 100th participant! To recognise this achievement and the incredible efforts across all participating sites, we will be awarding a prize to the site that recruits the 100th participant.

EQ-5D-5L Completion

It was noted in our last Trial Management Group meeting that completion rates for the EQ-5D-5L were low when compared with the number of participants recruited or attending their follow-up visits. Please complete the EQ-5D-5L with participants if you are able to. We are happy for the questionnaire to be completed with the patient up to two weeks before or two weeks after their visit, either in-house or remotely.

Screening Logs

Screening log data is requested at the beginning of each month for the previous month. Please return screening logs as soon as possible upon request as they are essential for our ongoing monitoring of site activity, recruitment progress and screening outcomes.

Screening logs help us assess the trial's eligibility criteria and determine whether any adjustments or additional support may be needed to enhance site performance and recruitment.

Changes to Staff & Delegation Logs

Please notify the BCTU Trial Team of any changes to staff as soon as they occur. If a staff member leaves the trial, this should be documented in the "Date of Duties to" column on the delegation log. If a staff member joins, please complete a new entry on the log. In both cases, an updated copy of the delegation log should be sent to the trial mailbox. A CV, GCP certificate and completion of training is also required before a new staff member can be approved to work on the trial.

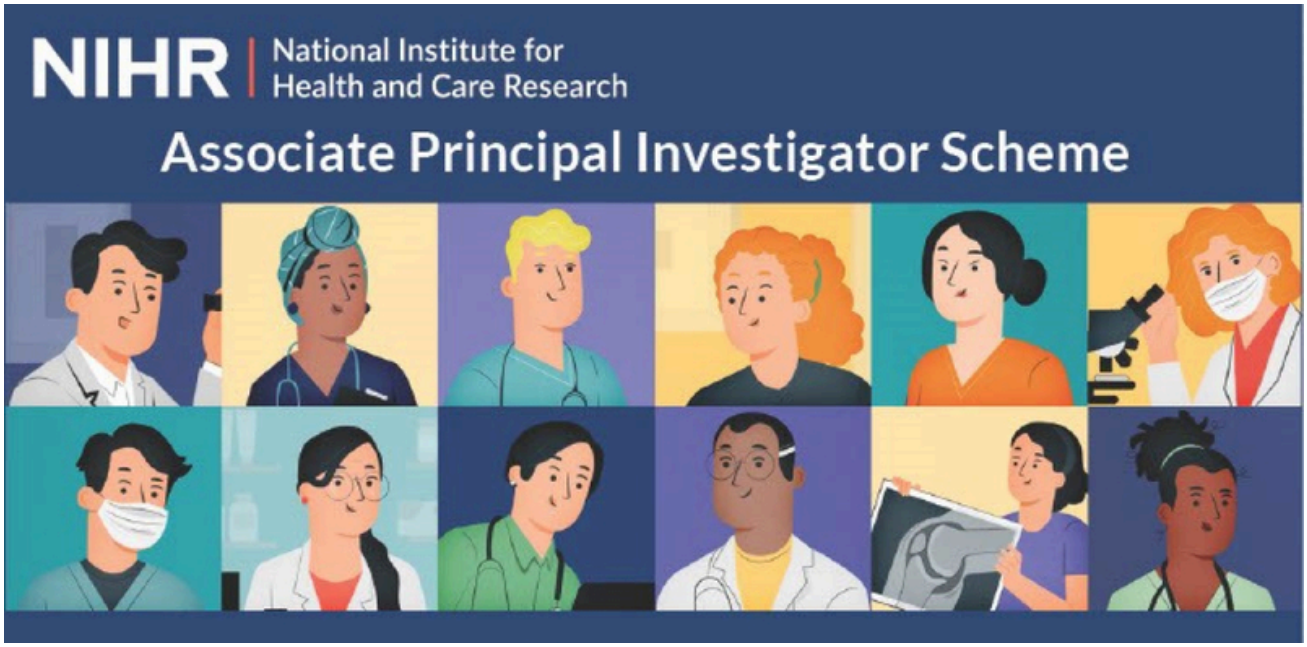
CVs & GCP certificates should be up to date as per local Trust policy, and we kindly ask that updated documentation is sent to the BCTU Trial Team as and when it becomes available.

SAE Reporting

A gentle reminder that **the only SAEs requiring expedited reporting** to the BCTU Trials Office **are participant death**, or SAEs outlined within Section 10.8 of the protocol in the event that a **participant falls pregnant**.

All other events should be recorded in accordance with relevant protocol guidance. Please consult Section 10.4.2 of the Protocol to assess whether an event meets the criteria for non-expedited reporting. If it does not, kindly refer to Section 10.4.1 for further instruction.

NIHR Associate PI Scheme



The REACT-AVB trial is registered with the Associate PI Scheme and is currently accepting applications.

The scheme provides clinical staff with the chance to experience what it means to work and deliver a NIHR portfolio trial under the mentorship of a Local PI. Participating staff will receive formal recognition of engagement in NIHR Portfolio research studies through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges.

For more information, please visit: Associate PI Scheme - FAQs | NIHR.

To register to become an Associate PI for REACT-AVB, please discuss your interest with the nominated PI at your site. Once agreed, you can submit your application via this link

Contact Us

Have any questions? We are happy to help!

REACT-AVB Trials Office

REACT-AVB Trial Team
Birmingham Clinical Trials Unit
Public Health Building
University of Birmingham
Edgbaston
B15 2TT

react-avb@trials.bham.ac.uk

CI/Co-CI Contact

dhiraj.tripathi@uhb.nhs.uk
david.patch@nhs.net