



REACT-AVB NEWSLETTER

**Randomised controlled trial of
Early transjugular intrahepatic
portosystemic stent-shunt in
Acute Variceal Bleeding**



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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 third REACT-AVB newsletter. We are very grateful to all collaborators for their contributions. REACT-AVB is very much your trial.

Since the last newsletter, REACT-AVB has completed the pilot thanks to your efforts. To date, there are 23 open sites and a number of others in set-up. We are aiming to open 30 sites. 67 patients have been recruited so far, thanks to the research teams working tirelessly to screen patients. We are hopeful that once all sites are open, recruitment will gather pace.

Another significant development is the protocol amendment, which you will all be aware of. We want to make it easier to recruit patients with fewer screening failures. We have increased the TIPSS time window from 4 days to 5 days. Other changes include extending the time window for follow-up visits and clarifying imaging requirements in response to site feedback. If you have questions about how these changes impact your site procedures or patient eligibility, please refer to the detailed guidance or contact us directly.

We are delighted to inform you that REACT-AVB has had excellent engagement with the Associate PI Scheme, with 18 APIs registered so far, and 6 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 be in touch with sites to arrange a one-to-one catch-up, as this has been very helpful to sites in the past.

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.

Merry Christmas and best wishes for the New Year.

With kind regards,

Dhiraj & David

Site Update

23 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!

Spoke sites recruiting: 8

- Whittington Hospital
- Good Hope Hospital
- Heartlands Hospital
- Gloucestershire Hospitals NHS FT
- New Cross Hospital
- Northwick Park Hospital
- Royal Cornwall Hospital
- St Thomas' Hospital



Sites in set-up: 9

- Addenbrooke's Hospital
- Freeman Hospital
- Kings College Hospital
- Worcestershire Royal Hospital
- Royal Victoria Hospital
- St James' University Hospital
- St Mary's Hospital
- University of Coventry
- University Hospital of Wales



Hub sites recruiting: 15

- Queen Elizabeth Hospital (Birmingham)
- The Royal Free Hospital
- John Radcliffe Hospital
- Queen's Medical Centre
- Royal Infirmary of Edinburgh
- Derriford Hospital
- Glasgow Royal Infirmary
- Queen Elizabeth University Hospital (Glasgow)
- Norfolk & Norwich University Hospital
- Northern General Hospital
- Southmead Hospital
- Queen Alexandra Hospital
- Aintree Hospital
- Manchester Royal Infirmary
- Royal Liverpool University Hospital



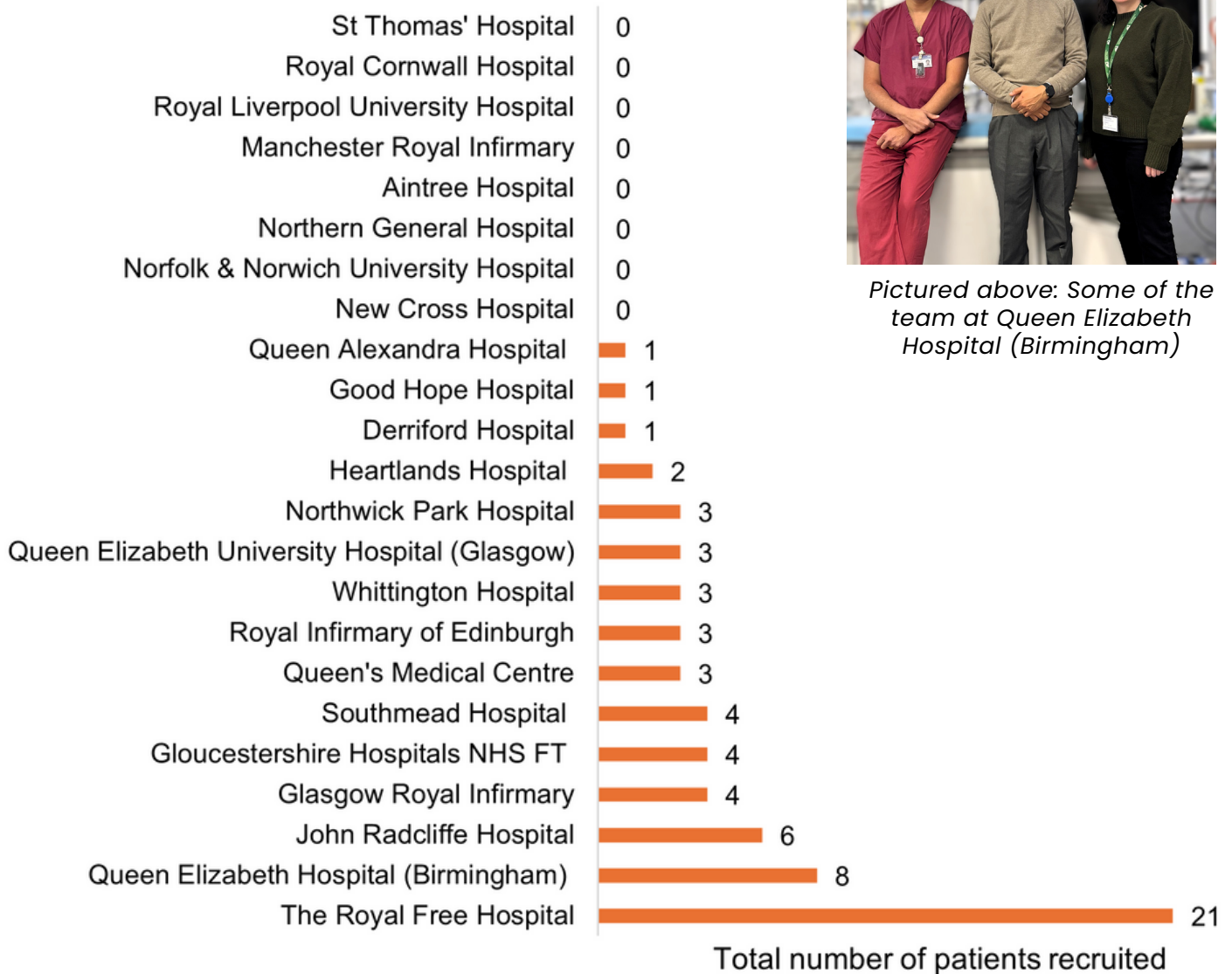
Recruitment Update

67 participants have been recruited into the trial across 23 sites!



Thank you to all open sites for your continued efforts in finding suitable patients to recruit. Data collated from the monthly screening logs shows that 332 patients have been assessed for eligibility since recruitment commenced.

Participant recruitment by site



Pictured above: Some of the team at Queen Elizabeth Hospital (Birmingham)

Steps to Green Light Approval

- ☀ Completed feasibility form
- ☀ Completed Organisation Information Document (OID)
- ☀ Fully executed site agreement (mNCA)
- ☀ Confirmation of Capacity & Capability
- ☀ Localised patient facing documentation
- ☀ Protocol signature page, signed by the PI
- ☀ Completed delegation log
- ☀ Signed and dated CVs & GCP certificates (in line with local Trust policy) for all staff on the delegation log
- ☀ All staff on the delegation log to watch the pre-recorded site initiation training slides (self-certification of training completion required via presentation link)
- ☀ Attendance at a live virtual Q&A session, mandatory for the PI and Associate PI prior to opening, but recommended for all staff involved in trial delivery

Updated Documents

Substantial Amendment 1

Notification of approval of SA1 was circulated to sites in early November. The new document versions we are working to are as follows:

- **Protocol:** v4.0
- **Main Patient Information Sheet:** v3.0
- **Recovered Capacity Patient Information Sheet:** v2.0
- **Consultee Information Sheet** (England/Wales): v3.0
- **Welfare Attorney / Welfare Guardian / Nearest Relative Patient Information Sheet** (Scotland): v3.0
- **GP Letter:** v2.0

If you have not yet returned your updated localised documents and/or updated protocol PI signature page, please supersede the old versions and send copies of the new versions to the trial mailbox as soon as possible. Please refer to the email correspondence for more detailed instructions.

Changes to Case Report Forms

The following Case Report Forms have also been updated, and we are now working to the following versions:

- **Randomisation** Form: v2.0
- **Baseline** Form: v5.0
- **SAE** Form: v2.0



Reminders & Housekeeping

Case Report Forms & Data Clarification Form Returns

Form return rates and resolution of data queries remain strong and we thank you for your continued engagement with the trial. Please keep an eye out for any outstanding assessment and/or DCF reminders.

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.

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.

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 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

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Keep up to date
with the trial via our
pages below:



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@AvbReact

**PLEASE NOTE THAT THE TRIALS OFFICE WILL BE
CLOSED FROM 4PM ON MONDAY 22ND DECEMBER
2025 TO THURSDAY 1ST JANUARY 2026 (INCLUSIVE).**

**PLEASE REFER TO YOUR EMAIL CORRESPONDENCE
FOR FURTHER DETAILS ON SAE REPORTING DURING
THESE DATES.**

WISHING YOU A VERY

MERRY
Christmas

AND A
HAPPY NEW YEAR

From the REXACT-ARB TMG

