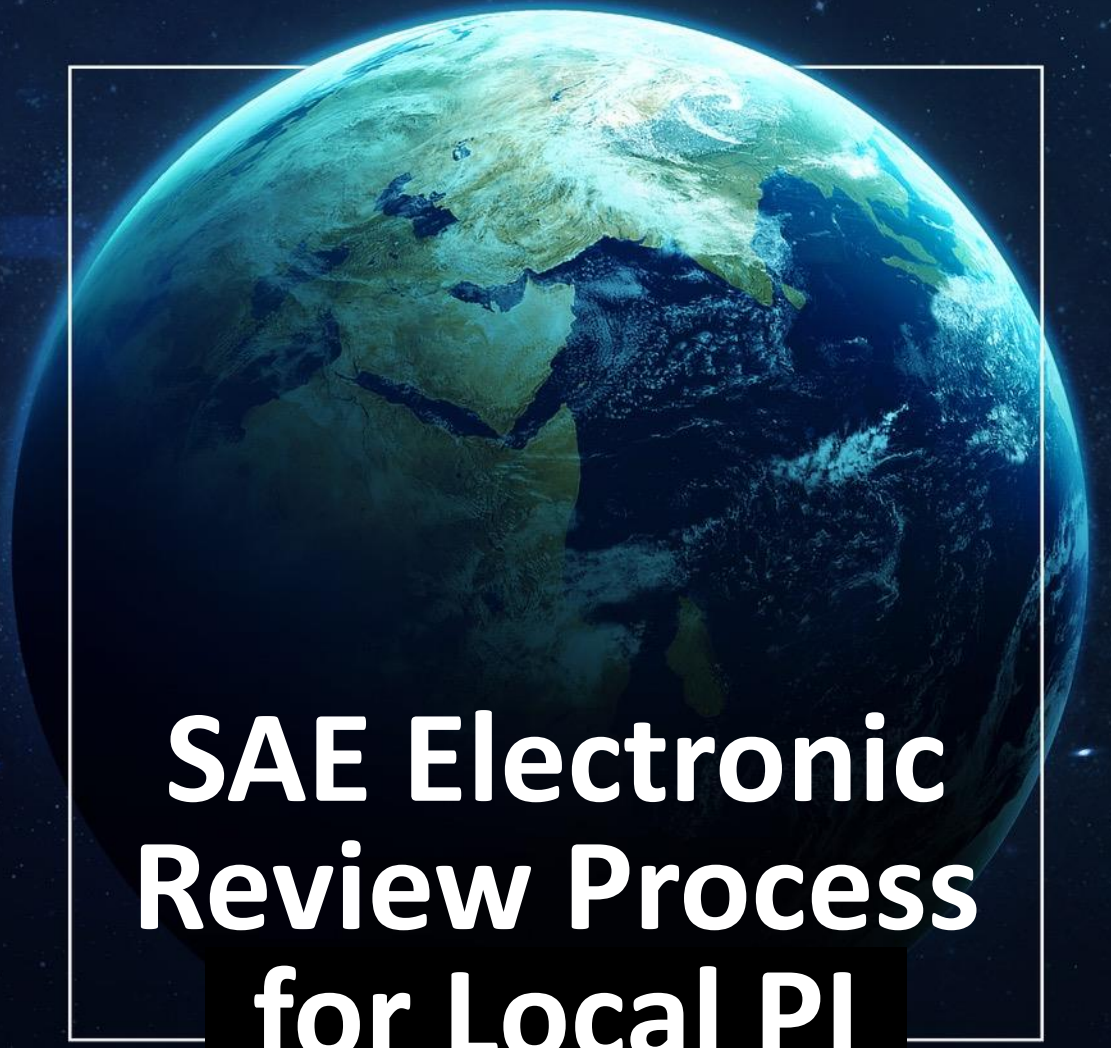
University of Nottingham
UK | CHINA | MALAYSIA



SAE Electronic Review Process for Local PI

Stroke Trials Unit, Nottingham

Final v1.0 06/12/2024

Previous process

The previous SAE review process generated an email alert that is sent to the local PI when an SAE form was submitted.

> As Principal Investigator at your site, please demonstrate that you have fulfilled your legal obligation in assessing this event for causality and relatedness to the IMP. Review and sign a printed copy of the SAE case report form (by printing this email), and ensure that the signed copy is filed in the trial site file.

If any data corrections were applied to the SAE form, the email alert would be sent again to the local PI to review again with the updated information.

However, following a sponsor review we have been asked to demonstrate how PI oversight is documented in TICH-3. Introducing this electronic system should simplify the need for PIs to print off SAE reviews.

Current process to be followed

We have now implemented an electronic review process which must be followed please.

1. SAE form submitted by delegated research team member
2. Email alert is generated to;
    a. Everyone who has entered data relating to the corresponding participant
    b. The local PI
    c. The coordinating centre
3. Local PI to assess the event for causality and relatedness to the IMP

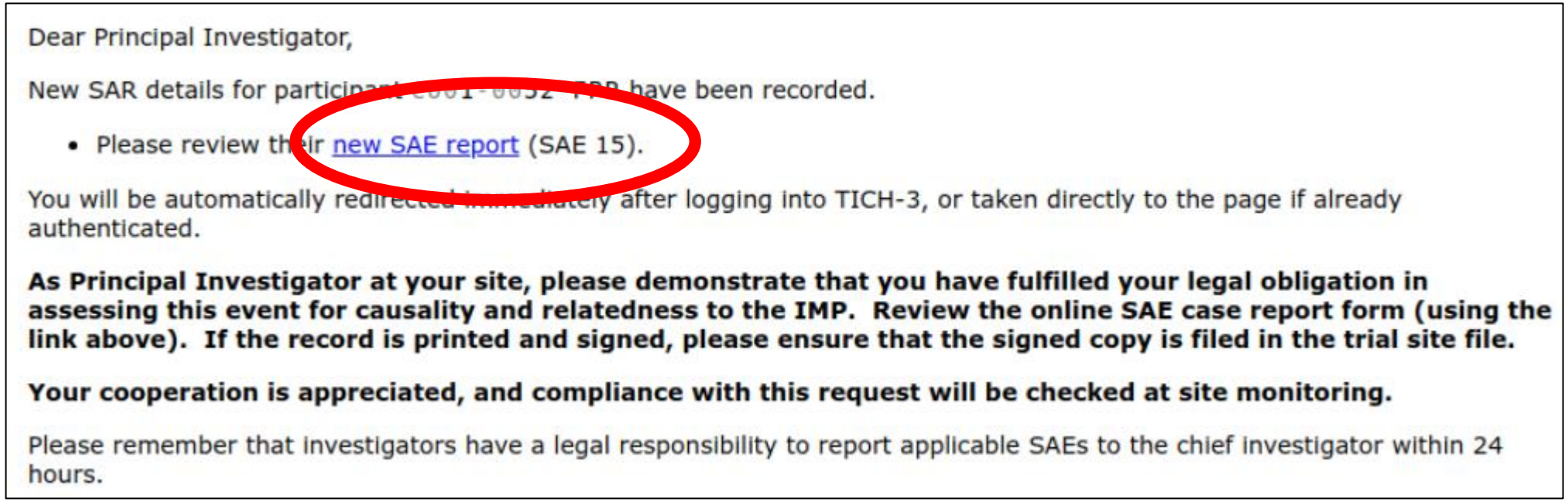
    SmPC is available on the TICH-3 documents page

    Focus Tranexamic Acid 100mg ml Solution for Injection Summary of Product Characteristics (SmPC) 20210202 REVISION.pdf

4. This review is now documented electronically (see next slides)

Electronic review process (1)

On the email alert there is a link for the local PI to complete the electronic review.



Dear Principal Investigator,

New SAR details for participant [illegible] have been recorded.

- Please review their new SAE report (SAE 15).

You will be automatically redirected immediately after logging into TICH-3, or taken directly to the page if already authenticated.

As Principal Investigator at your site, please demonstrate that you have fulfilled your legal obligation in assessing this event for causality and relatedness to the IMP. Review the online SAE case report form (using the link above). If the record is printed and signed, please ensure that the signed copy is filed in the trial site file.

Your cooperation is appreciated, and compliance with this request will be checked at site monitoring.

Please remember that investigators have a legal responsibility to report applicable SAEs to the chief investigator within 24 hours.

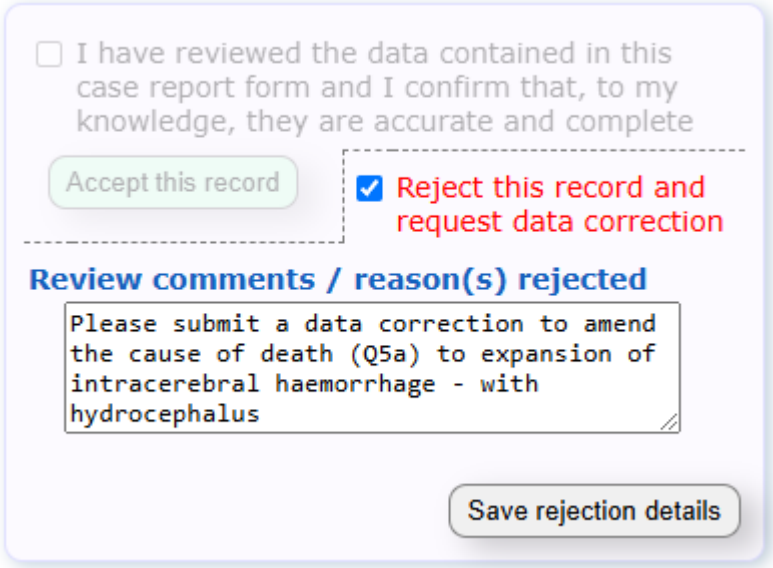
Click on the blue highlighted link ‘new SAE report’.

Electronic review process (2)

At the bottom of the eCRF you will now see a review dialogue box. You can either accept the SAE report (figure A) or reject the report (figure B) as more information is required e.g. cause of death

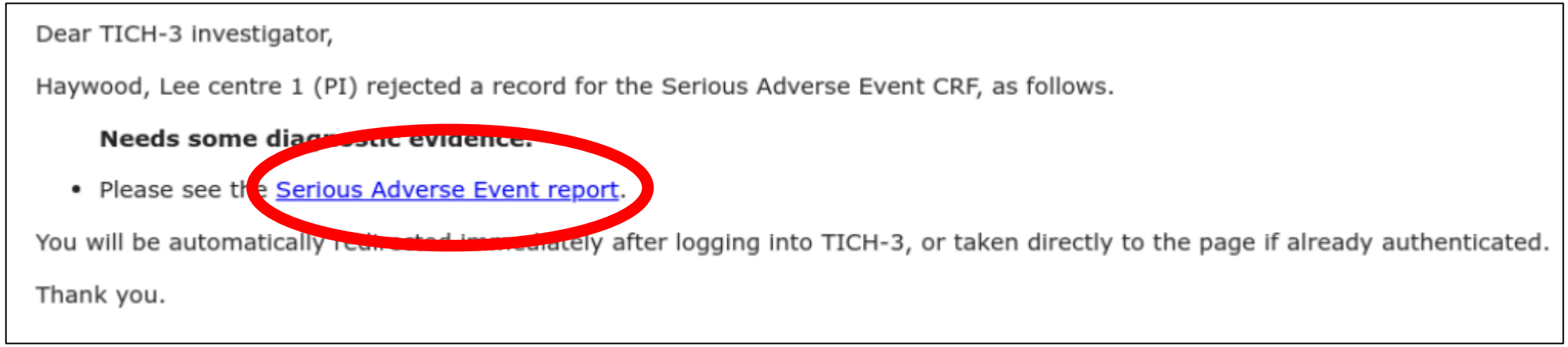
Figure A

Figure B



Electronic review process (3)

If the SAE report was rejected a data correction is required to add further information as requested by the local PI. This will generate another email to the local PI, everyone who has entered data relating to the corresponding participant and the coordinating centre.



Dear TICH-3 investigator,

Haywood, Lee centre 1 (PI) rejected a record for the Serious Adverse Event CRF, as follows.

Needs some diag[illegible]stic evidence.

- Please see the Serious Adverse Event report.

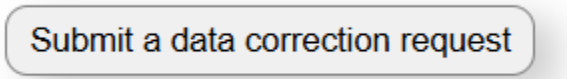
You will be automatically redirected immediately after logging into TICH-3, or taken directly to the page if already authenticated.

Thank you.

Electronic review process (4)

To complete a data correction to the SAE report the research team member will go back to the ‘serious adverse event report’ by clicking the link on the email or you can access through the participant list on the TICH-3 website https://stroke.nottingham.ac.uk/tich-3/live/

Please complete the data correction request as normal by clicking the ‘submit a data correction button’.



Please refer to guidance on submitted a data correction on the TICH-3 documents page Data corrections guidance Final v1.0 07.03.2023.pdf

Electronic review process (5)

Once the data correction has been submitted an email will be sent to the local PI, everyone who has entered data relating to the corresponding participant and the coordinating centre that re-review of the SAE form is now required.

Dear Principal Investigator,

Please **re-review** SAE number 15 using the link provided, following the changes described below.

- SAE number 15

For your records, a data correction that was requested on 5 Dec 2024 has been applied to the Serious Adverse Event CRF, for SAE number 15 (trial number 52).

The reason given for the change was as follows.

CRF review test.

The following comments were recorded by the trial office.

B1: Diagnostic evidence - changed from "Test" to "CT scan done on 4 Dec 2024 and blood results uploaded too.".

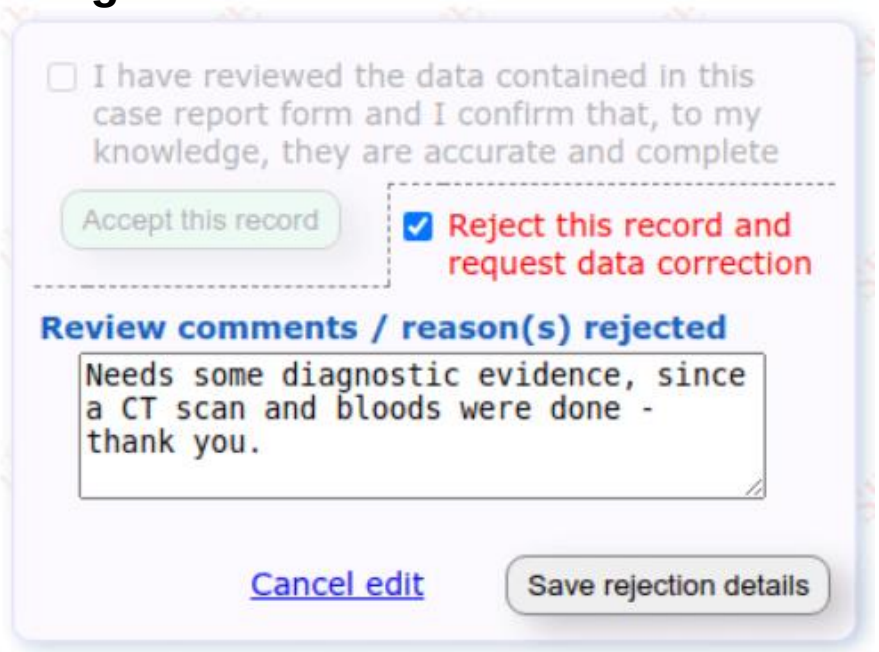
Thank you.

Electronic review process (6)

At the bottom of the eCRF you will now see the review dialogue box again. You can either accept the updated SAE report (figure A) or reject the report (figure B) as more information is still required e.g. diagnostic evidence.

Figure A

Figure B



Once the SAE form is accepted, the review process is complete.

Common queries

1. SAE forms can still be submitted by a delegated research team member (does not have to be the PI or deputy PI to submit the form) after they have discussed the safety event with the PI or appropriate medic

2. Only the local PI/deputy PI can review and then approve the SAE form

3. SAE forms are still also reviewed by the coordinating centres trial medic – we may ask for further details if required

4. You can still print the SAE forms if you wish, in line with the previous process, however we will require the electronic review to be completed

OPTIONAL REVIEW OF OTHER eCRFs

You will now see the dialogue box on all eCRFs (enrolment, day 7, death/discharge, protocol violations). The PI can review and document approval using the dialogue box but this is NOT REQUIRED on these eCRFs, only the SAE review by the local PI is required.