



Health Research Authority

2 Redman Place
Stratford
London
E20 1JQ

Tel: 020 7104 8100
Email: cag@hra.nhs.uk

19 October 2023

Niky Raja
Epilepsy12 Project Manager
Royal College of Paediatrics and Child Health
5-11 Theobalds Road
London
WC1X 8SH

Dear Ms Raja,

Application title: UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)

CAG reference: 17/CAG/0184

Thank you for your amendment request to the above audit application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process confidential patient information without consent. Supported applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Secretary of State for Health and Social Care on whether an application should be supported, and if so, any relevant conditions.

Secretary of State for Health and Social Care support decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group (CAG) as set out below, has determined the following:

1. The amendment, to allow the RCPCH (with Microsoft Azure as a sub-processor), to administer the Epilepsy12 database, instead of Net Solving Ltd, and for Epilepsy12 to collect data about only patients with a confirmed new diagnosis of epilepsy rather than a suspected epilepsy diagnosis, is fully supported, subject to compliance with the standard conditions of support.

Amendment request

The amendment sought support for the RCPCH (with Microsoft Azure as a sub-processor), to administer the Epilepsy12 database, instead of Net Solving Ltd. The new data platform is scheduled to launch in 2023 to begin collecting data on patients in cohort 6. The Net Solving platform will remain active until January 2024 to allow users to continue entering data on cohort 5 patients up until the January data submission deadline. After this deadline, data entry will be paused on the Net Solving platform, however users will still be able to access and view their data but will not be able to make any changes. All data on the new platform will be hosted in servers within the RCPCH environment using Microsoft Azure as a sub-processor.

There will be a 2-month window between December 2023 and January 2024 where both platforms will be live and collecting data – cohort 5 data on Net Solving and cohort 6 on the new platform - before the Net Solving is 'switched off' for clinical data entry and archived.

Epilepsy12 will now only request that patients with a **confirmed new diagnosis of epilepsy** are entered onto the new platform. Currently, Epilepsy12 capture all patients with a suspected epilepsy diagnosis at registration stage. Additionally, the dataset has been minimized. The data dictionary has been updated accordingly and has been provided. The Epilepsy12 webpages will be updated accordingly to highlight the change in data platform. An updated data flow diagram has been provided.

Launching this new data capture platform for Epilepsy12 will facilitate more engagement in the audit by NHS Trusts and Health Boards. As all audit data is manually entered onto the platform, there is a data burden associated with audit participation. The new system is designed to be easier to use and navigate, which, when accompanied with a minimised dataset, will lower the time needed to enter audit data and reduce the burden for clinical teams.

Confidentiality Advisory Group advice

The amendment requested was considered by Chairs' Action. The Chair was content with the changes requested.

A DSPT for Net Solving Ltd will be required until they are no longer processing any confidential patient information without consent.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

The NHS England **22/23** DSPT reviews for **Net Solving Limited, NHS England, Microsoft UK, Royal College of Paediatrics & Child Health**

and SysGroup PLC were confirmed as '**Standards Met**' on the NHS England DSPT Tracker (checked 19 October 2023)

Reviewed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>
Amendment Request Form		30 August 2023
Epilepsy12 amended external data flow diagram		
Data Dictionary 5.0	5.0	
Ref_ SCTASK0094824 - DSP Toolkit review for Royal College of Paediatrics and Child Health - 8HV48		13 October 2023

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Caroline Watchurst
Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: cag@hra.nhs.uk

Enclosures:

Standard conditions of approval

Standard conditions of support

Support to process confidential patient information without consent, given by the Secretary of State for Health and Social Care, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant, in addition to other national guidance.
4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities.
6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.
7. Audit of data processing by a designated agent is facilitated and supported.
8. The wishes of patients who have withheld or withdrawn their consent are respected.
9. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.
10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.
11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.