NHS
Health Research Authority

‘Section 251’ Support – Annual Review

It is a standard condition of support that an annual review is supplied every 12 months, from date of the final support letter, for the duration of the support to process confidential patient information without consent. Applicants should submit this 4 weeks in advance of their annual review due date. The annual review due date is specified under the ‘Next Review Date’ field for each application entry in the Register of Approved Applications. Please ensure all sections are fully completed to avoid invalidation.

Notification of changes through this Annual Review submission are not permitted and will not be processed nor receive support; changes are managed via a formal separate amendment process.

PIAG/ECC/CAG reference number:	17/CAG/0184
Full application title:	UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
Application type: research or non-research	Non-research
Date annual review was due: (If the annual review has been submitted after its due date, please include an explanation)	5/02/2025

Information sharing:

Applicants should be aware that data controllers, such as NHS England (previously NHS Digital), may wish to check whether an applicant has provided an annual review to the CAG, to ensure the applicant support to process information without consent remains active before the controller can process a request for data access. We will share confirmation with data controllers whether an annual review has been submitted or not, and whether it is valid, in order to facilitate local disclosure decisions.

1. Security arrangements

All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS England at each annual review. Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.

Processing takes place in:	**England**	**Wales**	**Scotland**
Security assurance provided by:	Data Security and Protection Toolkit (DSPT)	Caldicott Principles into Practice (CPiP)	Review by the Public Benefit and Privacy

	– by organisation or specific function	report/or Welsh Information Governance Toolkit – by organisation	Panel for Health & Social Care
Applicant should contact:	Exeter.Helpdesk@nhs.net	The Confidentiality Advice Team (CAT) cag@hra.nhs.uk	Public Benefit and Privacy Panel (PBPP) for Health & Social Care
How assurance is provided to CAG	1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS England to review the relevant DSPT self-assessed submissions 3. NHS England review the DSPT submission and confirm to CAG when 'Standards Met'	Relevant CPIP out-turn report/Welsh IG toolkit provided directly by DHCW to CAG	An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance.

For applicant completion:

Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHS England DSPT team reviewing the self-assessed submission. Please ensure you have contacted NHS England and asked them to review your submission. The annual review will not be valid until NHS England has reviewed the submission and confirmed its status as 'standards met'.

If confidential patient information is being processed by NHS England (previously NHS Digital), please select this box: ☐

Security assurance has already been provided for NHS England (previously NHS Digital) so please do not complete any details below for NHS England (previously Digital).

Organisation (Full name)	**ODS Code**	**Date self-assessment submitted to NHS England**	**Date NHS England confirmed assessment reached 'Standards Met**
Royal College of Paediatrics and Child Health	8HV48	Standards met. Published 21/06/2024	10/02/2025
SysGroup PLC	8K915	Standards met. Published 04/02/2025.	10/02/2025
Microsoft UK	8JH14	Standards exceeded. Published 19/06/2024.	10/02/2025

Is any processing of identifiable information taking place in Wales? **Yes.**
Is there any processing of identifiable information taking place in Scotland? **No.**

If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps.

2. Study progress

i. Conditions of support (if applicable)

Supported applications often have specific conditions of support, in addition to standard conditions of support. Applicants are expected to comply with all standard conditions of support by default to ensure the support remains active.

Please set out how you have met the conditions of support (expand box as required). This should include any difficulties experienced and mitigating action taken. Specific conditions of support are located in your conditional or final outcome letter

Please answer the following three questions and ensure you check the correct boxes for each question (double click on each box and select 'checked' where relevant).

1. ☐ **The application has no assigned specific conditions of support.**

Please note that if there are specific conditions of support (as per the outcome letters) that have not been reported against, this will invalidate the annual review and a new annual review will need to be submitted; this may jeopardise the status of support for those relying upon this lawful basis.

2. ☒ **The following provides an update against existing specific conditions of support.**

List each specific condition (expand as necessary) and explain how it has been met

Condition 1: **Support extends to England and Wales only.**

Epilepsy12 continues to currently extend to England and Wales only.

Condition 2: **Support is in place for a non-research purpose only to support the audit programme and does not extend to any use of the data collected via this application for research purposes.**

Epilepsy12 data is not used for research purposes, it is used for local, regional and national clinical audit and local provider service improvement.

Condition 3: **Provide a report at the time of first annual review of actual patient and public involvement and engagement activity which has been undertaken. This should explain how children and young people were involved in the project. If the responses given are negative, the CAG will take these into account when considering whether support should continue, or whether further actions are required.**

Between April - June 2018, members of the RCPCH CYP engagement team visited 10 epilepsy clinics across the country to undertake "clinic chats", and these were about "creating the best epilepsy service". Results from the clinic chats and family event days were collated, and incorporated into a booklet style report which is now available on the Epilepsy12 website.

The ‘clinic chats’ project was developed further by the children and young people working in support of the RCPCH Engagement Team and Epilepsy12 project team. They created a ‘Clinic Chat Checklist’ for services to review and assess the support they offer to young people for anxieties and worries and have been piloting this since late 2019 with 8 paediatric epilepsy teams. In 2020/2021, the group visited six of these clinics virtually and hope to get more paediatric epilepsy services involved and host in-person or virtual visits.

The Epilepsy12 CYP engagement activities have been driven by young people themselves supported by the College CYP Engagement Team. Their engagement work received recognition via receipt of the inaugural Richard Driscoll Memorial award on two occasions in October 2018 and November 2022, recognising their outstanding, robust and sustained patient engagement in developing clinical audit and in reporting outcomes for patients. In 2020 the Epilepsy12 Youth Advocates were named National Volunteers of the Year in the HQIP Audit Heroes awards for their work with services to improve mental health support for children with long-term conditions. They were also celebrated in the 2023 HQIP Clinical Audit Awareness week, where they were announced as joint winners of the Patient and Public Involvement Hero Award.

Additionally, the Youth Advocates have held sessions at Epilepsy12/OPEN UK National Conferences, produced an Example School Individual Healthcare Plan, multiple patient resources, such as the 2022 Young Person & Parent leaflet, and have contributed to Epilpesy12’s application for exemption to the NHS National Data Opt-out. The group have agreed their priorities and plan for Round 4, and Epilepsy12 will continue to seek the Youth Advocates’ input into future audit activities.

Condition 4: **Provide an overview of further engagement work which had been undertaken in relation to patient notification materials to support the audit programme, together with copies of the finalised documentation, at the time of first annual review.**
The aim of Epilepsy12 is to help to improve the standard of care for children and young people with epilepsies. To do this, the audit collects and processes patient identifiable data to highlight areas where hospitals and clinics are doing well, and identify areas of improvement. For Round 4, Epilepsy12 has created a flyer which can be displayed in clinic areas and shared with patients, parents and carers to introduce the audit and signpost the full privacy notice.

The RCPCH and Epilepsy12 project team members take their responsibilities for maintaining the security of patient identifiable data extremely seriously. The project team created a detailed Epilepsy12 Privacy Notice in English and Welsh, in conjunction with the patient organisations represented on its Project Board and Methodology and Dataset group. The Privacy Notice is available to download via the Epilepsy12 web pages.

Epilepsy12 was granted an exemption to applying the NHS National Data Opt-out by CAG in January 2023 and has subsequently communicated information regarding the NDO to Health Boards/Trusts, stakeholders, patients and their families and the public. Communication routes included newsletters, emails, messaging on our website and producing a one-page flyer.

Condition 5: **Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission.**

- Royal College of Paediatrics and Child Health shows a ’standards met on the 2023/24 submission.
- The Royal College of Paediatrics and Child Health back up provider SysPro (SYSGroup PLC) show a ‘standards met’ on the 2024/25 submission.
- Microsoft UK show a ‘standards exceeded on the 2023/24 submission.

The Epilepsy12 Information Governance Checklist is updated regularly and submitted to the audit’s commissioning body, HQIP. The information is up to date and will next be submitted by 31 March 2025 for HQIP’s annual review.

Net Solving Ltd. previously developed and administered the Epilepsy12 data platform, and used a server provided by Rackspace to host the platform. Contracts and previous CAG approval was in place for both.

On 19 October 2023, CAG approved the request to move away from the Net Solving platform, and instead collect and report audit data on a bespoke RCPCH-hosted data capture system. The new platform was launched and began collecting data in December 2023.

All data on the new platform is hosted on servers within the RCPCH environment using Microsoft Azure as a sub-processor, in alignment with the above approved amendment request. The new platform has maintained high data security by replicating the user permissions from the Net Solving platform to restrict access to only approved personal, as well as introducing additional features such as 2-factor authentication, captcha processes and database encryption. A comprehensive Data Protection Impact Assessment (DPIA) has been performed and additional Penetration Testing carried out with all recommendations actioned. DPIAs and Pen-Testing are reviewed annually.

As described in the amendment request, the Net Solving platform remained active for a while, in order for audit data to be collected and processed for the 2024 annual report. Once analyses was completed, the Net Solving platform was discontinued, with all audit data securely on 1 November 2024. A certificate of destruction was completed by Net Solving and shared with HQIP.

The Epilepsy12 project team has direct assess to the database within the new platform through the RCPCH environment using Microsoft Azure. This access is restricted to only the data analyst working on the project. Only pseudonymised data and aggregate results are stored within the Epilepsy12 files, compared to the previous process of downloading all, including patient identifiable, data from the Net Solving platform and saving these locally.

Aggregated results, and associated files, are stored on the Microsoft Cloud in Microsoft UK data centers based in Cardiff, Durham and London with data backup provided at the Microsoft UK South (London) data center. The datacenters have international security certification, including ISO 27001, and technical security features such as multifactor authentication, regular penetration testing and is encrypted with at least one AES 256-bit keys and distributed across the datacenter using TDE. Data from the new platform will follow this process.

CAG approved the request to move all Epilepsy12 files from the RCPCH network drives to Microsoft 365 (SharePoint) on 13 June 2022.This migration was completed in April 2023, and the back-ups were deleted from RCPCH network drives in October 2023 (6 months after migration). Files were transferred from the RCPCH network to restricted access SharePoint sites using a tool called ShareGate, run by an IT admin at the College. RCPCH have a contract with ShareGate and neither Sharegate nor the member of staff making the transfer access any data being migrated. Access in SharePoint is the same as the network drive, where access is restricted to the audits team with IT staff having administrative access to all sites. All staff receive SharePoint training, and staff will not be able to share any information from the site externally.

3. ☒ I can confirm the application adheres to all the standard conditions of support.

ii. Steps taken to anonymise the information or obtain consent from individuals

What steps have been taken to reduce the identifiability of the information or seek consent from the patients? If this has not been done yet, please confirm at what stage you intend to or the reasons why you are not going to.

Identifiable data is fully encrypted on the data platform server. The data platform has restricted and secure access, including multi-factor authentication. Only approved users from participating Trusts/Health Boards are granted access and can view identifiable data for the purpose of clinical care and service improvement, but only for patients within the care of their own service.

Whilst the current CAG approval permits the RCPCH to process patient identifiable information without consent for the purpose of Epilepsy12, patients or their parents can indicate to their care team that they wish to opt out of the audit. Their data is then not entered onto the platform. If they have already been registered onto the platform, they can request their record to be deleted through their clinical team or by contacting Epilepsy12.

This opt out process is separate to the NHS National Data Opt-out (NDO). Epilepsy12 were granted an exemption to applying the NDO on 10 January 2023. All patients meeting Epilepsy12 eligibility criteria are therefore entered into the audit, regardless of NDO status, however patients can still opt out of Epilepsy12 directly via the process described above.

The project team have included information on our website and in our communications to patients and parents about the audit, how the data will be used, how the NDO exemption operates and how to opt out by informing the epilepsy service.

iii. Projected end date

What is the expected end date for your study; **this is the date by which all confidential patient information is no longer identifiable and support is no longer required**.

The RCPCH has been commissioned by HQIP to deliver Round 4 of the Epilepsy12 audit from 1 April 2022 up until 31 March 2025. A duration amendment covering this period was submitted and approved by CAG on 22 March 2022.

RCPCH was awarded a 2-year extension, to continue delivering Epilepsy12 until 31 March 2027. A separate duration amendment will be submitted to CAG to cover this period before March 2025.

Beyond that point no identifiable data would be retained for analysis purposes unless the contract is extended with all related governance approvals in place via the HRA.

iv. Project changes

Please provide a summary of any formal amendments made to the CAG that have been supported.

It is important to note that only those details specified in the original application (and any formal amendments) have been supported. For applications supported over 5 years ago, or where the application detail no longer reflects current activity, a new application may be required.

The following amendments were submitted and supported by CAG:

- Duration amendment to cover duration of new Epilepsy12 contract (Round 4) up until 31 March 2023 [22.03.2022]
- Data items amendment to allow:
  - the addition of patient ethnicity to data items,
  - the removal of Rackspace as a data processor,
  - and the change of physical storage location within the RCPCH for storage of Epilepsy12 files used for data processing and analysis – to the Microsoft Cloud in Microsoft UK data centres based in Cardiff, Durham and London with data back up provided at the Microsoft UK South (London) data centre,
    [13.06.2022]
- Deferral request to applying the National Data Opt-Out [10.01.2023]
- Change in data capture system from Net Solving ltd. to an RCPCH hosted platform [19.10.2023]

3. Justification for ongoing support

i. Practicable alternatives/exit strategy

It is a requirement of the Regulations that applicants review the requirement to continue processing confidential patient information without consent on an annual basis. Please provide an overview of alternatives being considered or taken to remove the need for ongoing support, such as the receipt of anonymised data only or the movement towards a pseudonymised approach.

Epilepsy12 have continued to explore ways to improve the experience of those submitting data to the audit and reduce the associated data entry burden. The new platform has a minimised dataset, incorporates new technology to enhance usability and navigation through the platform and offers both prospective and retrospective data entry throughout the audit year. The live patient performance summaries and performance reporting dashboards provide users with real-time feedback on quality of care, which can highlight data entry errors and potential gaps in patient care, facilitating the rectification of both before the year of care is complete. The new platform allows enables services to track performance throughout the audit year, as well as benchmark against peers and regional and national averages, which feeds into quality improvement initiatives including PDSA cycles.

The new platform continues to collect patient identifiable information. It would be possible to amend the Epilepsy12 data platform so that only anonymised data could be captured through the system however, as per the original application, the Project Board and Methodology and Dataset group believes that doing so would detract from the ability of participating Health Boards and Trusts to use the many data platform functions which help them to monitor and improve services and patient care.

4. Patient and public feedback

Please provide details of any complaints, queries or objections that you have received from patients (which specifically relate to this application to process confidential patient information without consent) and the steps you have taken to resolve them. Have any patients requested that their data is not processed and how has it been ensured that this has been respected?

Between 2018 and its discontinuation in 2024, almost 43 thousand children and young people were registered onto the old Net Solving Epilepsy12 platform. To date (30 January 2025), 6224 children and young people have been registered to the new platform. Very few (<100) had “patient opted out” status as indicated by their Trust before the NDO was applied in July 2022, and even fewer recorded have an opted-out status following the exemption.

In August 2018, Epilepsy12 received one direct request via its mailbox from someone who asked that their baby’s data be deleted from our database. The RCPCH Information Governance Manager wrote to the person in question and to verify their guardianship for the baby; RCPCH did not receive a response. The request has been recorded on the Rights Request log held by the Information Governance Manager. As an additional note, no-one with the name used in the request email had been registered onto the data platform by any of the participating Trusts.

We are continuing to review our website and communications to ensure the process for handling rights requests in relation to our audits is clear, that parents and participants are aware to ask their service directly where they wish to be opted out of the Epilepsy12 audit, and that the information for the NHS National Opt-Out is shared with services, individuals inputting data and patients.

5. Public benefits

To support the need for continued support, applicants should set out what public benefits have arisen since support has been in place, and from time of last annual review. Support to process confidential patient information without consent is based upon there being a public interest in the activity proceeding so applicants should consider this section carefully. Applicants should set out what public benefit has been achieved, or whether a public benefit is still anticipated.

Epilepsy12 was designed to stimulate national improvements in the diagnosis of seizures, and on-going treatment and support for children and young people with epilepsy. Epilepsy12 has aimed to improve the consistency of care, by strengthening regional knowledge, skill and resource sharing in the OPEN UK (Organisation of Paediatric Epilepsy Networks in the UK) regional paediatric epilepsy networks. Epilepsy12 hosts the national meetings of OPEN UK (bringing all the regional leads together), jointly hosts the annual conference with OPEN UK, and provides regional analysis and comparison data via a dashboard on the data platform and in our annual reporting.

Epilepsy12 is included in national policies as a key vehicle for change, where services can use audit metrics to measure against standards and recommendations. The key performance indicators (KPIs) used by Epilepsy12 are mapped via clear ‘lines of sight’ with the NICE guidelines on ‘Epilepsies in children, young people and adults’ [NG217, updated April 2022], and NICE Quality Standards [QS27, updated December 2023]. Through the organisational audit Epilepsy12 is able to provide key insights into how the current workforce reflects the expectations of those standards. The clinical aspect of the audit examines how care and outcomes compare to the national guidelines. Health improvement goals have been set based on audit findings and are therefore year on year increases in the percentage of children and young people with epilepsy receiving care in line with national expectations and best practices.

The results of Round 3 of Epilepsy12 have been published in 2019, 2020, 2021 and 2022. Round 4 results were published in 2023 and 2024, with scheduled publications in Summer 2025.

These analyses have highlighted a number of areas of improvement in care, for example in the 2024 annual report:

- More children with epilepsy had specialist input into their care from both Epilepsy Specialist Nurses (81%) and paediatrician with expertise in epilepsy (92%) compared to previous years. However, only 51% saw a paediatrician with expertise within the NICE recommended 2 weeks.
- There was widespread use of care planning, with 81% of children and young people with epilepsy having evidence of an updated and agreed comprehensive care plan. Although, only 65% had a care plan with all core components.
- Most Trusts/Health Boards (91%) had agreed referral pathways to adult services and 68% had joint-working between paediatric and adult teams by routinely involving adult epilepsy specialist nurses in the transition of young people from paediatric to adult services.
- Almost all children and young people with epilepsy received an EEG investigation, however only 54% received one within 4 weeks of referral.
- 37% of children and young people with epilepsy who met surgical referral criteria had a referral to Children’s Epilepsy Surgery Service (CESS) during their first year of care.
- Few epilepsy services could provide co-located mental health provision as recommended within the Best Practice Criteria (18%).
- Only 22% of children and young people with epilepsy aged 5 years and over had evidence of assessment of mental health issues. This indicator ranged from 19.1% in the most deprived group to 27.6% in the least deprived group.

There was still need for considerable improvement in some areas in order to meet national standards, and reduce variation between services at regional and local levels. National recommendations have been made to target both improved access to key services and an increased specialist workforce to support children and young people with epilepsy. These will be monitored and reviewed in light of future findings.

Epilepsy12, as the only national programme investigating paediatric epilepsy care, plays an important role in measuring and improving quality of care and outcomes. We are aiming for all Health Boards and Trusts providing care to children and young people with epilepsy in England and Wales to participate within Epilepsy12, however participation has not improved considerably since cohort 1, and remains static around 75%. The audit project team is working with OPEN UK regions and NHS England ICBs (Integrated Care Boards) to promote the audit, alongside streamlining data entry to minimise associated data burdens, to encourage participation.

The Epilepsy12 audit is also supporting the work of the NHS England Epilepsy Oversight Group, which was formed by the NHSE CYP Transformation program in line with the Long-Term Plan. The group used Epilepsy12 data to define four priority areas, which are also aligned with audit performance metrics and improvement goals, and create a National Bundle of Care for Epilepsy to describe key standards and recommendations to support systems with epilepsy quality improvement within these areas.

1. Access to mental health screening & psychosocial support,
2. Transition from paediatric to adult epilepsy services,
3. Access to tertiary services, including epilepsy surgery,
4. Variation in care provided.

Epilepsy12 will continue to support the Epilepsy Oversight group by providing annual data on key audit metrics, and more frequently if requested, to help inform improvement and planning, and help shape the recommendations made by these working groups. From 2023, Epilepsy12 data is also reported at ICB and NHSE region, in addition to Trust/Health Board and national levels.

In July 2023, Epilepsy12 launched a frequent reporting dashboard to display aggregated performance data on key audit metrics at local, regional and national levels in the public domain. Results were initially updated quarterly, and are now refreshed on a monthly basis. These outputs allow healthcare professionals, commissioners, stakeholders, patients, families and the public to interact with audit data and utilise results to inform planning and quality improvement. The dashboard is also replicated on the new data platform, where approved users can view real-time data on performance measures to aid in benchmarking, improving data quality and rectifying potential gaps in patient care.

In 2019, Epilepsy12 initiated a pilot quality improvement collaboration of 10 paediatric epilepsy services; the Epilepsy Quality Improvement Programme (EQIP). Drawing on the audit intelligence, local data, and quality improvement training teams are working together to implement a quality improvement project to improve care and services. A second round was delivered in 2021/22, a third wave in 2022/23 and a forth wave ran from October 2023 to August 2024. Teams present their findings, successes and learns learnt at a celebratory event at the end of each program to promote shared learning. Impact reports describe the benefits of the programme and be found online. Unfortunately, the EQIP has not been re-commissioned for a fifth wave, however resources and case studies can still be access online to support teams.

The public benefits of the audit include better quality of life of children and families with epilepsy as a result of improved care, transparency around the performance of different hospitals and Trusts, and empowering families to demand better care and appropriate access to support or services. It is also expected that improvements in care will result in healthcare savings associated with later avoidance of complications associated with poor seizure control, inappropriate medications or treatments**.**

5. Confirmation of contact details

Please confirm contact details for the publicly available register of approved applications.

☒ The contact details below are the same as those currently published in the Register of Approved Applications.

☐ The contact details below are NOT the same as those in the Register of Approved Applications. In order for this change to be processed the reason for this change must be specified here.

The reason for the change to contact details is as follows:

Name of controller for application: **Royal College of Paediatrics and Child Health**

Contact Name and role: **Niky Raja, Epilepsy12 Project Manager**

Full address:
Royal College of Paediatrics and Child Health
5-11 Theobalds Road
London
WC1X 8SH

Telephone: 020 7092 6056

Email: niky.raja@rcpch.ac.uk

Named applicant Name: Niky Raja

Signed: Niky Date: 04/02/2025

Please return this completed form to cag@hra.nhs.uk. Questions over completion should be directed to cag@hra.nhs.uk

Please note this document will be assessed by the Confidentiality Advice Team in the first instance. Depending upon the content, the team might request further information, arrange a subsequent meeting to discuss the content of the annual review, or escalate to the Chair or to CAG.