Health Research Authority

Annual report for the Confidentiality Advisory Group

1 April 2025 – 30 March 2026

Chair Foreword

I officially started my term as CAG Chair in November 2026 and was very grateful for the 3-month hand over period with the outgoing Chair, Dr Tony Calland.

You will see that the performance of the CAT and CAG, according to the KPIs, has been excellent again this year. This is due to the hard work of Paul Mills, the CAT team and all of our volunteer CAG members.

These KPIs only show part of the work of CAG. We are in a period of rapid change within the health data space, with reform of the COPI regulations and the, National Data Opt Out, commencement of the Health Data Research Service and other emerging developments that may impact how health information is used for secondary purposes. The CAG are, in principle, very supportive of changes that improve the safe access and use of health and care data, for the benefit of patients, the public and the NHS.

CAG plays a very specific role in the health data system to enable the safe and transparent use of health information, and we should be working within clear Policy positions. However, there have been occasions this year when CAG has been in the situation of potentially making policy through precedent, especially in relation to the Secure Data Environments (SDEs). The SDEs have been very keen to progress quickly including sharing of data for multi SDE projects and more recently recruitment to clinical trials and other primary research studies. Of utmost importance is the maintenance of public trust – whilst many of the SDEs have undertaken public engagement, there is a real hesitancy to be transparent about the use of confidential patient information that underpins their functioning.

CAG have worked with other key stakeholders, including HRA colleagues National Data Guardian, NHS England and DHSC to confirm the current policy position and develop a process that enables the SDEs to progress with these multi SDEs initiatives if they are being transparent with, and involving, the public in a proportionate and appropriate way. We are aware that there will be new initiatives from the SDEs, for example recruitment to clinical trials and other research. These new initiatives will require further work for clear policy positions to be in place, and I look forward to working with HRA colleagues to ensure these positions will retain public trust.

CAG have valued having the opportunity to comment on the COPI and NDOO reforms, but it would be good to see that these DHSC teams working together with HDRS team to progress these changes soon.

As well as the Chair, Tony Calland, leaving this year, two of our very longstanding Alternative Vice Chairs, Clare Sanderson and Murat Soncul have also stepped down. We are very grateful to them for their dedication and input to CAG over the last 13+ years.

I would like to end by thanking Paul and the CAT team, the CAG Chair team and CAG members for their dedication, hard work and support over the last year.

Professor Lorna Fraser

CAG Chair

1. Introduction

This report provides an overview of the activity of the Confidentiality Advisory Group (CAG) during the period from 1 April 2025 to 31 March 2026. It also outlines the work undertaken by the Confidentiality Advice Team to support and develop the CAG, to streamline the application review process, as well as support legal and policy reform within the health data landscape throughout the reporting period.

The report supports the HRA Board in monitoring CAG and CAT performance.

The CAG reviews research and non-research proposals to ensure that they conform to recognised standards and enables the safe and transparent use of Confidential Information Patient Information without consent. CAG operates under the Health Service (Control of Patient Information) Regulations 2002 and enables activities to be undertaken where they would otherwise not be able to, whilst maintaining public trust in the safe use of health data.

All applications to CAG involve the use of confidential patient information without consent and outside the care pathway. However, this encompasses a variety of different uses of Confidential Patient Information. The most common type of applications are those linking different datasets across England and Wales (54%). Other types of applications include providing direct access to medical records (14%) and use of identifiable information to invite a cohort to consent into a research study (12%)

Whilst CAG has both a research and non-research function, most of the activity is research at 79%. Within this research context, most is academically sponsored (68%) with NHS-sponsored research making up a significant minority at 23%. CAG sees a much smaller proportion of commercially sponsored research at 3%.

2. Key highlights

The year 2025-2026 has been a positive one which saw many achievements. Below are the key highlights mapped specifically against the pillars of the HRA Strategy for 2025-2026:

Simple

For researchers to find out how to do research with and for everyone and access support to do this well

Fast

To plan, approve, set up, manage and complete research in the UK

Performance

The CAG review pathway is operating efficiently according to the data in this report, with 99% of full applications processed within the target time, and a median time for review of 27 days, well within the 60-day target. Of course, this is the time that application is with the CAG service and does not include the time the applicant has an action.

Working with NHS England

Of the research applications that involve linking of multiple datasets, 77% involved datasets held by NHS England. The usual involvement is for a source to provide HS England the identifiers of a cohort, with NHS England returning the requested clinical information of these patients.

We are committed to unblocking any aspects of the regulatory process that may cause issues for applicants. One specific area that has historically caused delays is where CAG and NHS England data access reviews have been done separately, leading to a number of queries raised subsequent to CAG approval. In some situations, this has unfortunately led to applications running out of funding before data was received, due to the delays.

In the past year however, we have started working much more closely with the team to enable queries to be handled between HRA and NHS England teams rather than via the applicant. An example of some of the types of activity undertaken in the past year include:

- Knowledge share sessions between staff from both organisations to understand roles, processes and considerations better.
- Knowledge share sessions between the CAG Chair Team and NHS England's Advisory Group for Data (AGD – their data access committee) to understand areas of review and remit.

- Regular meetings established between Confidentiality Advice Service Manager and service leaders of the data access request service (DARS) to understand broader points of issue.
- Encouraging DARS to raise and CAG queries early and directly, and vice versa.

We are seeing the benefits of this positive relationship building, which has also provided more understanding and assurance about CAG processes, with more direct DARS queries come through that we are able to support collaboratively.

Digital intermediaries

Following publishing of the HRA report on "Using health information to let patients know about research options: legal, policy and ethical issues", CAG considered its first application on digital intermediaries. These are organisations (which can be commercial or non-commercial) offering services that allow potential research participants to be found using information from NHS organisations and General Practices.

The application has been approved after careful consideration by CAG, which enables the applicants to use their services for a range of research projects that require ethical review only. Importantly, the review provided rich information on expectations of digital intermediaries, which will be a useful precedent and reference when considering similar future applications.

Trusted
By everyone who needs us

System reform

The system that underpins the safe and transparent use of patient information for secondary purposes, including research, is undergoing a period of legal, policy and system reform. Whilst being led by other key organisations, CAG have provided early input into all these alongside the HRA, and will continue to do so as necessary. A summary of activity to date includes:

Health Service (Control of Patient Information) Regulations 2002

These Regulations (commonly called the COPI Regulations) underpin the use of confidential patient information without consent, and the role of CAG. They are over 25 years old and are in need of updating to ensure continued relevance in today's world.

The CAG chair team, alongside the HRA, has provided initial input into early proposals by the Department of Health and Social Care (DHSC) and await next steps.

Opt out reform

The opt out system includes the national data opt out, Type 1 opt outs and project specific opt outs. Each opt out applies differently and it can cause confusion to the public. The national data opt out, in its simplest form, applies to any application under Regulation 5 support, following CAG advice, but is a blunt instrument. As such, the DHSC are reviewing the policy position around opt outs.

In relation to this:

- DHSC has twice spoken to CAG at specific meetings to seek the perspectives and views of our CAG members, who bring invaluable insight on opt outs
- Confidentiality Advice Service Manager attended two workshops in Autumn 2025, providing key input to help DHSC scope views
- Confidentiality Advice Service Manager invited to be part of a DHSC expert advisory panel to guide opt out reform, which demonstrates the value that the CAG perspective can add

We currently await next steps from DHSC.

Health Data Research Service

The Health Data Research Service (HDRS) was announced by the Government in Spring 2025 and will ultimately provide opportunities to reform the way that health data is safely accessed and used for research.

HDRS is still early in its development but the CAG Chair, alongside senior staff in the HRA was able to meet with the HDRS chief executive in Spring 2026 by way of an introduction and offered further expertise and support.

National Data Guardian

The National Data Guardian is a key stakeholder that operates in a similar space to CAG, and who hold the same values. As such it is vital we establish and maintain good relationships.

The CAG chair has quarterly meetings with the National Data Guardian and the chair of NHS England's Advisory Group for data. As well, the Confidentiality Advice Service manager, alongside the HRA Data and Privacy Specialist, regularly meet with the Office of the National Data Guardian.

In both meetings issues and opportunities of the day are discussed, as well as ongoing or upcoming work which may need each other's input. It facilitates consistent understanding of the data landscape and further action where needed.

NHS England

The Confidentiality Advice Service Manager was invited by NHS England to speak to researchers at an event in November 2025 to provide an overview of the CAG service. This enabled attendees to undertake the CAG role more and expectations to help prepare applications.

Effective
Taking action to improve research system and support our people well

Chairing

During the year Dr Tony Calland stepped down as CAG Chair, with Prof. Lorna Fraser replacing him. We appointed Lorna early to have a transition period of about 3 months where Lorna and Tony worked together to enable a smooth transition.

CAG development day

We brought CAG members together for a development day in October 2025. It provided an opportunity for members to meet in person and reconnect, as well as allowing members to discuss pertinent topics of the day. This included discussions with DHSC on the data landscape and bitesize learning sessions.

Secure Data Environments

CAG has approved many of the Secure Data Environments (SDEs) and during this period attention has turned to support the SDEs with ongoing developments to enable effective operation and researcher access to data.

One of the big areas of work has been on multi-SDE projects (where SDEs sharing data between each other) for research that required data from more than one SDE. Whilst there have been challenges at times, we participated in a meeting with DHSC and NHS England, chaired by the National Data Guardian. We have since provided guidance to the SDEs on a proportionate approach to the regulatory requirements of multi-SDE projects and are working with the network on this.

We consistently offer to work with the SDE network to discuss potential issues early to limit any delays in implementing new approaches.

Contributing to REC member learning

We continually run learning sessions every 3 months for REC members who want to learn more about CAG. This enables REC members to have confidence on the CAG process and supports cross learning across the HRA volunteers to help support the review process. This training was originally started in 2021 and has proved popular, meaning it is now a session that we provide regularly.

3. CAG membership

Requirements

CAG undertakes broadly the equivalent work of two Research Ethics Committees, and aims for a maximum membership of 30. CAG members are comprised of lay and expert members, with definitions of each below:

- Expert members - represent a range of backgrounds, including clinical, research and information governance
- lay members - provide a range of expertise and viewpoints from outside the expert areas.

Quoracy for full CAG meetings was seven members. At any one meeting, it is usual practice to have 2 members of the chair team who share the chairing of applications.

CAG membership

At the end of March 2026, CAG had 25 members, comprising 15 expert members and 10 lay members.

Whilst we have maintained stable numbers over the year, there has been natural flux with four members resigning (3 expert and 1 lay) and four members recruited (2 expert and 2 lay). Of the four who left, three had been with CAG for over 10 years and the final CAG member competing demands on time. The replacement of long-serving members brings in new views and expertise, whilst also dealing with the challenge of losing past knowledge. HRA staff play a key role to ensure relevant information is provided to CAG as needed.

CAG Chair Team

The CAG Chair team has and are undergoing a period of change. Long-serving CAG member and Chair, Dr. Tony Calland, stepped down in October 2025, and was replaced by Prof. Lorna Fraser. Tony provided a long notice period which enabled Lorna to be appointed and work alongside Tony for a period of months prior to his departure. This allowed for a smooth transition of chairing responsibilities. Lorna is leading CAG well and proving to be a strong voice for CAG in many arenas.

Alongside Lorna, Mr Dan Roulstone, a lay member, was appointed as vice chair. Dan has taken to chairing or meetings well, and it has been invaluable to have a lay voice on the chair team to help support CAG and Lorna.

Since the end of the reporting period, a further two long-serving alternate vice chairs have stepped down, and a new alternate vice-chair has been appointed. Like with members, it is key for staff to ensure that consistency is maintained, whilst encouraging the natural development of CAG through new ways of operating.

For assurance, changes in the chair team are arising primarily due to long service of the members leaving and the CAT team is proactively undertaking succession planning as part of maintaining the service.

4. CAG reviews

Applications reviewed at full CAG meetings

Applications for full CAG meetings are discussed online by the CAG, with applicants invited to attend the meeting to discuss the application. The Key Performance Indicator (KPI) for full meetings in 2025-26 was to issue a final outcome within 60 calendar days of a valid submission. The table below summarises performance:

Type of Activity	Number Reviewed	Median time to final decision	% reviewed in less than 60 days	% reviewed in 60 days difference to 2024-25
Research	54	28	98	↑ 5%
Non-Research	18	23	100	↑ 5%
Total	72	27	99	↑ 5%

Performance against the KPI was excellent, with one application given a final outcome outside the 60-day target,

Applications reviewed at precedent set CAG meetings

In contrast to full meetings, applications to precedent set meetings are considered by a sub-committee of the CAG through correspondence. Applications need to meet a precedent set criterion to be considered through this pathway. The Key Performance Indicator (KPI) for precedent set meetings in 2025-26 was to issue a final outcome within 30 calendar days of a valid submission.

Type of Activity	Number Reviewed	Median time to final decision	% reviewed in less than 30 days	% reviewed in 30 days difference to 2024-25
Research	43	24	79	↑ 9%
Non-Research	8	15	88	↑ 13%
Total	51	23	80	↑ 9%

Performance in precedent set meetings improved compared to the previous year, primarily due to improved staff performance.

Amendments

Type of Activity	Number Reviewed	Median time to final decision	% reviewed in less than 35 days	% reviewed in 35 days difference to 2024-25
Research	152	9	96	↓ 3%

Non-Research	50	7.5	96	↓ 4%
Total	202	9	96	↓ 3%

Performance against target (final outcome issued within 35 days of a valid amendment) is excellent at 96%, though a slight decrease in performance compared to last year. In total, eight amendments missed the KPI target.

As a proportionate approach, amendments are either reviewed by the Confidentiality Advice Team alone or are assigned individually to CAG members. More complex or significant amendments are reviewed by full committee. Five applications met this threshold, and all were reviewed within the target of 60 days for full review.

Annual reviews

Type of Activity	Number Reviewed	Median time to register update	% reviewed in less than 30 days	% reviewed in 30 days difference to 2024-25
Research	360	19	98	↑ 8%
Non-Research	112	19.5	95	↑ 4%
Total	472	19	97	↑ 7%

As part of the regulations that CAG operate under, it is a requirement for applicants to annually consider the need for ongoing support, and submit an annual review. Each annual review is reviewed by the Confidentiality Advice Team, with a small proportion escalated to CAG. The target is to update the Registers of Supported Applications on the HRA website within 30 days of valid submission.

Over the past three years we have established a consistent mechanism to proactively contact applications that are overdue their annual review. Doing so has subsequently increased the number of annual reviews submitted to 472 this year, up from 297 in 2022-23. This also provides assurances to organisations and the public that applications operating under support continue to work within the scope of support and have met any conditions, in accordance with regulatory requirements.

Performance in meeting the KPI target was excellent at 97% overall

5. CAG advice

Advice given at CAG meetings

When considering an outcome to advise CAG have a number of options available. These are the same for both full and precedent set meetings. These are below, along with the percentage given at the meetings across 2025-26, with data from Research Ethics Committees (REC) given as a comparison

CAG outcome type	% given at CAG	REC outcome type	% given at REC
Supported	5	Favourable Opinion	8
Supported with Conditions	23	Favourable Opinion with conditions	17
Provisional	70	Provisional	70
Deferred/Rejected	2	Unfavourable Opinion	4

A description of the outcomes available are as follows:

- Supported – the application has the approvals in place to begin
- Supported with conditions – the application has the approvals in place to begin, but has some conditions to respond to. These may be minor, specific alterations to documents or could be to provide updates at annual review.
- Provisional – the application has queries or actions to progress and cannot yet begin. The queries/actions need to be addressed before a final outcome is given.
- Deferred – it is unclear on the scope of the application and CAG cannot advise an outcome based on information provided. Applicant can reapply.
- Rejected – whilst the applicant is clear, CAG do not believe it is in the public interest for the applicant to be supported. Applicant can reapply addressing the issues raised.

The level of outcome types given is consistent with that of RECs in every outcome type. 28% of applications are given a supported outcome (either fully or with conditions) at the first meeting. Only 2% of applications are deferred by CAG, with none of these being a rejection. This demonstrates CAG's commitment to enable research to happen where it is otherwise unable to. The small number (3) of applications that are deferred are due to significant uncertainties on the scope and request of made by the applicants. These all have the opportunity to reapply, and CAG will provide advice on what further information is necessary.

Application decisions

The CAG provides expert independent advice that is considered by either the HRA for research applications or the Secretary of State for Health and Care (SofS) (via the Department for Health and Social Care) for non-research applications. The HRA or SofS take the final decision on applications and amendments to access patient information without consent using the CAG advice as the initial basis for the decision. Below shows how many decision are taken for application across the year.

	Number
Research decisions taken by the HRA	267
Non-Research taken by the SofS	76

Total decisions	343

The table shows that 78% of activity considered by CAG relates to research. This follows the same trend as previous years. During this period there were no instances where the decision-maker substantively disagreed with the CAG advice.

Note that the table does not solely relate to decisions on initial applications and amendments. Some annual reviews may be considered by a decision maker as well as other ad hoc situations.

Advice requests by NHS England

There is a statutory requirement for NHS England to seek advice from CAG on matters relating to the use of confidential patient information. No requests for advice were received from NHS during the period.

Appeals

No requests for reconsideration by CAG was received, following the initial application being rejected, because there were no instances of rejection by CAG.

Applications that are deferred all have the opportunity to reapply, with additional staff support provided.

Breaches

A breach is a report by the applicant or a third party of activities that are counter to the support and conditions in place. CAG follows the HRA breaches process and liaises with REC for research activities.

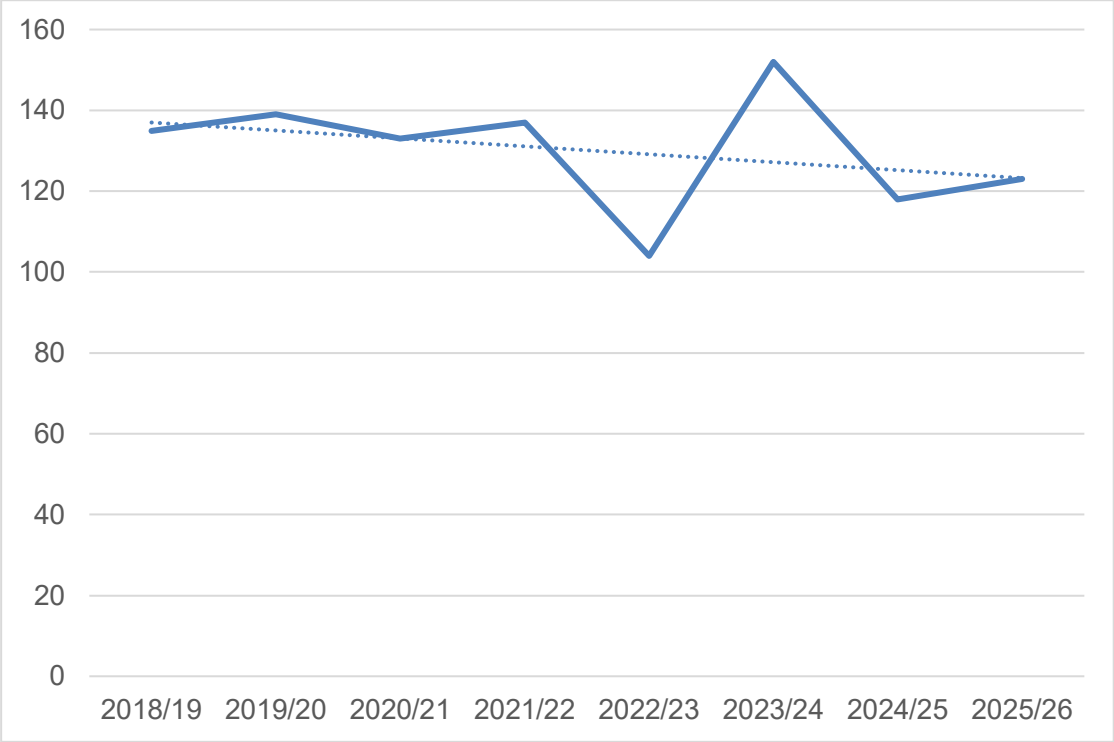
During 2025-26 CAG received reports of seven breaches. The types of breaches reported to CAG predominantly covered two areas:

- Accidental sharing of identifiable information
- Incorrect (or lack of) application of the national data opt out or Type 1 opt out

6. Identifying trends

Whilst comparing data with the previous reporting period is helpful, reviewing data over a longer period helps to identify trends and informs business planning. Looking at the data over a period of five years, we can see the following:

- CAG membership is stable, though with a frequent turnover of volunteers it relies on regular recruitment. In 2020-21 72% of CAG members were expert members and the annual report noted a target to shift that balance to 55% expert members and 45% lay members. Currently we are at 60% expert members and 40% lay members, which seems appropriate.
- Application numbers show a slight decline in numbers across the years, as shown below:



The slight downward trend in application numbers generally mirrors that seen in REC, with a slight increase seen this year compared to the previous year.

- Performance against KPI targets has significantly improved compared to 2020-21:

	2020-21	2025-26	Change
Full applications	82%	99%	↑ **17%**
Precedent set applications	60%	80%	↑ **20%**
Amendments	91%	96%	↑ **5%**
Annual Reviews	69%	97%	↑ **28%**

This is primarily due to having a settled and now more experienced team supporting the CAG.

7. Conclusion

This report demonstrates that during 2025-26 CAG enabled the use of Confidential Patient Information without consent in a timely and supportive manner, and in a way that provided public trust to this use. CAG members and staff should be proud of these achievements and the HRA extends its thanks to all involved.

It also highlights the range of stakeholders and policy developed that CAG interacts with and provides valuable inputs on. This reflects the trusted position that CAG has in the system, with expertise sought from CAG on a range of areas.

Looking ahead, priority areas for CAG and the service in the coming year include:

- Maintain and improve the service provided to CAG applicants, considering feedback when received.

- Review and update applicant guidance to support applicants in getting it right first time to further shorten the time to be able to start. Areas of particular focus will be public involvement and patient notification.
- Support development of the content strategy which will complement the updating of guidance.
- Continue to support and input on continue legal, policy and system reform in the health data landscape.
- Supporting the ongoing development and rollout of the Plan and Manage Health and Care Research digital platform.
- Aligning where appropriate with changes as a result of the Clinical Trials Regulations to provide consistent process and terminology for applicants.
- Implementing the HRA's Target Operating Model.
- Exploring and applying artificial intelligence to support the work of the Approvals Directorate and CAG members.