Monthly record of activity of the Confidentiality Advisory Group

October 2026

This document sets out the monthly activity of the Confidentiality Advisory Group, outside of full and precedent set meetings. It details:

Requests for further information of new applications

Response to CAG conditions

Modification outcomes

Annual Reviews supported

Applications which have been expired

The activities are a mixture of CAG sub-committee, CAG Officers or Confidentiality Advisory Team, and each section will summarise the advice routes available

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1. New applications (request for further information)

Responses to requests for further information are generally considered by a sub-committee of the Confidentiality Advisory Group and each application below will confirm the review arrangements, aligned with the agreement made at the initial meeting.

1.1	**26/CAG/0076**	**Clinical Cardiovascular Imaging Database**
	Chief Investigator:	Professor Thomas Treibel - Applicant
	Sponsor:	University College London Hospitals NHS Foundation Trust
	Application type:	Research Database

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair
Dr Malcolm Booth	CAG Expert Member
Mrs Catherine Bernadette Trigwell	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from University College London Hospitals NHS Foundation Trust set out the purpose of creating a research database, to be used to support research into diagnosis, prognosis, risk stratification, and treatment outcomes in cardiovascular disease using advanced imaging.

This study aims to establish a large, multi-centre UK cardiovascular imaging research database by combining routinely collected clinical, imaging, and linked outcome data from patients who have undergone clinically indicated cardiovascular imaging. By integrating pseudonymised imaging and healthcare data across several NHS centres, the database will support research into the diagnosis, prognosis, risk stratification, treatment outcomes, and long-term progression of cardiovascular disease, as well as the evaluation of novel imaging techniques, with the ultimate goal of improving understanding of cardiovascular conditions and informing future patient care.

Imaging data with no confidential patient information has previously been collected. The applicants are now seeking support for NHS number and date of birth of these patients to be shared from the five participating sites to University College London Hospitals NHS Foundation Trust (UCLH). UCLH will subsequently share these identifiers, along with a study id, to NHS England and OneLondon to request data, which is returned with study ID only and then linked together in the UCL data safe haven.

Confidential information requested

Cohort	Patients that have undergone clinically indicated Cardiovascular imaging (echocardiography, Cardiac CT, Cardiac MRI) imaging at participating centres, including University College London

	Hospital (UCLH), Royal Free London NHS Foundation Trust, Imperial College Healthcare NHS Trust, Barts Health NHS Trust, and Chenies Mews Imaging Centre. Estimated to be approximately 17,500 per year
Data Sources	1. Electronic patient records at participating sites. 2. NHS England • Hospital Episode Statistics (HES) • Medicines Dispensed in Primary Care (NHSBSA) • Civil Registration of Deaths 3. OneLondon
Identifiers required for linkage purposes	• NHS Number • Date of birth
Identifiers required for analysis purposes	Date of death (MM/YYYY only)
Additional information	Identifiers to be held in the database: • NHS Number • Date of birth • Date of death (MM/YYYY only)

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	The CAG request for further public involvement to be conducted with a patient advisory group: a) Discuss the use of CPI in conducting the study and gather feedback from PAG members. b) Provide additional information on the demographic makeup of the PAG, ensuring it is	Following the meeting, patient and public involvement was expanded beyond the original valvular heart disease group to include established groups at UCLH and Barts Health, ensuring broader representation of people with cardiovascular conditions. A total of 16 people contributed, providing feedback on the proposed use of confidential patient information, NHS England data linkage, study safeguards, and

	representative of the study population. Present all patient notification materials to the PAG for review and update them as appropriate.	patient notification and opt-out materials. Feedback led to several improvements, including clearer explanations of data linkage and de-identification processes, greater prominence of the opt-out process, additional information on study duration and results, and confirmation of opt-out request acknowledgements. Participants supported the use of confidential patient information for this non-commercial research, recognising its potential to improve understanding of cardiovascular disease, treatment decisions, and patient outcomes, and no concerns were raised regarding the proposed approach. The CAG noted this and raised no further queries.
2.	Review the patient notification materials to ensure all abbreviations are either clearly defined at first use or removed where unnecessary.	Revised materials were provided. These were reviewed and accepted by the CAG.
3.	Confirm that the NDOO will be applied before data disclosure from any of the five sites.	The applicants advised that they will request each participating site to use the NHS England MESH service to apply the National Data Opt-out before transferring data to the Sponsor, ensuring that any patients who have opted out are excluded at the earliest stage. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice: ***Fully supported***

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority subject to compliance with the standard conditions of support.

Number	Condition
1.	Favourable opinion from Cambridge Central Research Ethics Committee. **Confirmed: 22 April 2026.** A modification has been submitted to the REC to add the linkage of imaging data with clinical outcome data from NHS England and Integrated Care Record systems, undertaken with s251 support. This was given favourable opinion on 03 July 2026.
2.	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 **25/26** DSPT review for the following organisations was confirmed as 'Standards Met' on the NHS England DSPT Tracker: • Royal Free London NHS Foundation Trust • Imperial College Healthcare NHS Trust • Barts Health NHS Trust • University College London Hospital

1.2	**26/CAG/0057**	**Using real-time medical record data to identify rates of nephrotoxin co-prescribing and associated Acute Kidney Injury in hospitalised children**
	Chief Investigator:	Dr Louise Bracken
	Sponsor:	Alder Hey Children's NHS Foundation Trust
	Application type:	Research

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair
Mr Anthony Kane	CAG Lay Member
Ms Kim Keltie	CAG Expert Member
Mr Umar Sabat	CAG Expert Member

Also in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from Alder Hey Children's NHS Foundation Trust set out the purpose of medical research to develop and test a simple, easy-to-use digital tool that shows in real time how often children in hospital are given medicines that may affect their kidneys, how often kidney problems occur as a result, and whether this tool is practical and helpful for healthcare staff to use in everyday care.

This study is being undertaken because acute kidney injury (AKI) is a common and serious complication in hospitalised children, particularly among those receiving multiple nephrotoxic medicines, and there is currently no UK system to identify and manage this risk in real time. Evidence shows that giving three or more nephrotoxic drugs substantially increases the risk of AKI, especially in vulnerable groups such as cardiology, haematology, and oncology patients, while children from more deprived backgrounds may face additional, understudied risks. By developing a real time digital AKI Dashboard to track nephrotoxin use and kidney function, the study aims to enable earlier identification of at risk children, support safer prescribing, prevent avoidable harm, and improve understanding of how socioeconomic factors influence AKI outcomes.

A mixed methods design will be used to develop an AKI Dashboard, that identifies children at risk of acute kidney injury related to nephrotoxic medicines. Routinely collected electronic patient record data for all children admitted to Alder Hey Children's Hospital will be analysed, including prescribing, laboratory results, demographics, and postcode linked deprivation indicators, with exclusions for those who opt out. The dashboard will be iteratively developed using daily data extracts and refined through feedback from doctors, nurses, and pharmacists participating in interviews or focus groups. Quantitative analyses will describe medicine exposure, AKI incidence, and variation by specialty and socioeconomic status, while advisory group input will inform design, interpretation, and dissemination. All data will be handled securely, with appropriate pseudonymisation and anonymisation.

A recommendation for class 1, 2 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential information requested

Cohort	Children and young people (CYP), aged 0 – 25 years of age admitted to Alder Hey

	Children's Hospital during the study period.
Data Sources	• Electronic patient records held within Alder Hey Children's NHS Foundation Trust
Identifiers required for linkage purposes	• NHS Number • Hospital ID • Date of birth • Date of death • Postcode – unit level
Identifiers required for analysis purposes	• Date of birth • Date of death • Postcode – unit level • Gender • Ethnicity

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	REC Favourable Opinion in place on 17 June 2026.
2.	The CAG note that the dashboard will be used entirely for research purposes (and not for direct patient care or quality	The applicants confirmed that they understood that the AKI Dashboard will only be used for research

	improvement). In these circumstances, the expectation is for patient data to be removed from the dashboard where the National Data Opt Out or individual opt out is applied. However, the data flow diagram and the study documentation indicated that this will not be done. It is acknowledged that there may be some technical limitations in preventing the data flow from inpatient admission (via the EPMA system) to the dashboard. There should however be provision within the Trust to ensure that the NDOO status can be checked before the data is used for research purposes; please confirm that this will be done.	purpose during this study. The applicants acknowledged the expectation that the NDOO is applied, but explained that the technical configuration means that all patient data recorded within the EMPA system as part of routine clinical care will flow automatically into the AKI dashboard at the point of inpatient admission and it is not currently possible to stop this initial transfer. The applicants instead suggested that the study team performed the relevant checks for NDOO and applied the local opt-out before any dashboard data is used for research purposes. No data for opted-out patients will be included in the final dataset used for analysis. The CAG was not satisfied with the initial response and requested further justification for not applying the NDOO and an explanation of the technical reason why it can't be applied need to be provided. The applicants advised that applying the NDOO at the point of data flow is not technically feasible for a live, continuously changing inpatient dataset; therefore, opt-out checks are applied before research data extraction to ensure affected patients are excluded from the final dataset. The standard NHS England NDOO process is currently being applied via MESH as an interim solution, with weekly NHS number submissions and removal of any patients with an active opt-out prior to inclusion in the research dataset. A separate holding

		area is not required, as the research AKI Dashboard will only be updated retrospectively after NDOO checks have been completed and opt-out records removed. The proposed future API will not change the methodology but will automate the same NDOO checks within the dashboard data pipeline, enabling real-time application once NHS England implementation is complete. The CAG noted this and accepted the proposal, with the conditions noted below.
3.	Further public involvement should be conducted that is relevant to the study population. In particular, this should involve children and their families. Further involvement should also involve consultations on how the data is used, the purpose of the data use, and how patients can opt out. The group need not necessarily consist of children with (or previously with) AKI, but it should be representative of the population and include children.	The applicants undertook additional public engagement with children, young people and families at Alder Hey, including patients and families from inpatient wards. Feedback was provided in the document *Response to CAG (v1.0 15.06.2026) PDF* Feedback from this PPIE activity was used to further refine the study documentation, including the data opt out poster and additional information sheet, and to improve the clarity and transparency of information provided about data use in the study. Information regarding both study-specific opt-out arrangements and the National Data Opt-Out has therefore been incorporated into the study materials and communications. The CAG noted this response and raised no further queries.
4.	The CAG note that not every patient with AKI is expected to be readmitted, but ask what the estimated drop out will be, and if	The applicants acknowledged that some patients who experience AKI may be readmitted to hospitals outside the Trust and therefore not

	this could affect the study validity or intentions. Please confirm.	captured in subsequent data. This represents a limitation in identifying later AKI events rather than a loss of primary study data. The study relies on routinely collected inpatient data from standard clinical care, with the dashboard serving only to present existing prescribing and clinical information to support identification of associations between nephrotoxic medication exposure and AKI. No additional interventions or follow-up are introduced, and AKI detection and management remain the responsibility of the usual clinical team. As all relevant data from the index admission at Alder Hey are retained, and no additional study-specific follow-up is required, participant drop-out is not anticipated. While external follow-up data may be incomplete, this is not expected to materially affect the study's aims, which focus on inpatient associations and evaluation of the AKI dashboard as a clinical tool within Alder Hey. The CAG noted this response and raised no further queries.
5.	The CAG note that the poster has a QR code linking to the website. Please provide the data that will be linked to this QR code, and confirm if this content has been reviewed by a public involvement group.	The applicants explained that the QR code displayed on the study opt-out poster will link the reader directly to the additional information sheet. The additional information sheet is a new document developed specifically for this study. It was adapted from a participant information resource used in the Glycopyrronium bromide study (IRAS: 325926 / CAG: 23/CAG/0051), which was reviewed by CAG in 2023.

		The additional information sheet and study poster were reviewed by the Parent Champions group, a peer support initiative that helps families access healthcare, housing, and funded childcare services. On 09 June 2026, five Parent Champions and two Community Navigators working across Family Hubs and Children's Centres in the Liverpool region reviewed the study data opt-out poster and additional information sheet. Feedback focused on the clarity, readability, and accessibility of the documents. Further details on the feedback are given in the *Response to CAG (v1.0 15.06.2026) PDF.* The CAG noted this response and raised no further queries.

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	Within one month of the issuing of this letter, provide confirmation that no data will leave the Trust without patients' NDOO status being checked.
2.	Progress with the development of the alternative methodology needs to be reported at the next annual review.
3.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. **Confirmed:** REC Favourable Opinion in place on 17 June 2026.
4.	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 **25/26** DSPT reviews for **Alder Hey Children's NHS Foundation Trust & University of Liverpool** were confirmed as 'Standards Met' on the NHS England DSPT Tracker.

1.3	**26/CAG/0078**	**National Audit of Dementia - Memory Assessment Services**
	Contact:	James Campbell
	Data controller:	The Royal College of Psychiatrists
	Application type:	Non-research

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair
Mrs Catherine Trigwell	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from The Royal College of Psychiatrists set out the purpose of undertaking a national audit to measure and benchmark metrics of quality in Memory Assessment Services.

The National Audit of Dementia (NAD), commissioned by the Healthcare Quality Improvement Partnership (HQIP) under the National Clinical Audit and Patient Outcomes Programme (NCAPOP), will run from January 2025 to December 2027 on behalf of NHS England, the Welsh Government, and the Government of Jersey. The NAD aims to improve the quality, consistency and timeliness of dementia diagnostic and post-diagnostic care across England by measuring service performance against key evidence-based standards and driving continuous improvement through benchmarking and shared learning. The project focuses on five priority goals: reducing waiting times for diagnosis, increasing access to diagnostic imaging through PACS, reducing unwarranted variation in dementia subtype diagnosis, increasing access to Cognitive Stimulation Therapy (CST), and improving post-

diagnostic monitoring and support. Using routine data and a set of core audit metrics, NAD will provide services with comparative performance data through an interactive dashboard and national reporting, helping identify areas for improvement, promote good practice, and ultimately improve outcomes for people living with dementia and their carers.

A recommendation for class 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential information requested

Cohort	All NHS-funded adult patients referred to Memory Assessment Services in England.
Data Sources	Mental Health Services Dataset (MHSDS), held by NHS England.
Identifiers required for linkage purposes	No items of confidential patient information will be required for linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information will be required for analysis purposes.
Additional information	The applicants don't require specific items of confidential patient information. Support is sought because one of the required fields is *CareProfTeamLocalID*, a free text field which NHS England have assessed as presenting a risk that confidential patient information may be input in error and disclosed. There is no way of ascertaining in advance if any confidential patient information has been included. However as a free text field there is no way of ascertaining in advance if this has occurred.

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	The CAG request that the following changes to the patient-facing materials: (a) Simplify where possible. Consideration should be	(a) The applicants explained that this had been considered with the Lived Experience Reference Group and their feedback applied to the documents.

	made as to whether all 4 documents are necessary of if some of these can be merged. (b) Ensure that any QR codes link to information that states only the NDOO can be applied, as at present the information states that both a local opt out or NDOO may be applied (see action 2). (c) Update to state that the public can access Trust or team level data, and not just national level data. (d) Remove or explain any abbreviations and technical language. (e) Revise any language stating the project is approved by the HRA. As a non-research study, this should instead refer to the Secretary of State.	(b) Only information about the NDOO was included. If this request receives approval, this will be explained within the National Audit Privacy Notice with a link to the information sheet (c) This was updated and the information about reporting simplified. (d) Abbreviations, and language such as "pseudonymous" where not explained were removed. (e) This was amended. The revised materials were reviewed and accepted by the CAG.
2.	The CAG request that public-facing documents should be sent for further public involvement review, as there were some acronyms and other content that was perhaps more complex than was necessary, and may benefit from further review.	The applicants convened a meeting of the Lived Experience Reference Group to discuss all the aspects of the information and how it should be provided. This was attended by 5 people living with dementia and 2 carers. The group agreed that the information should be simplified and shortened and the format considered. An overview of their comments was provided. The CAG noted this and raised no further queries.

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	The CAG noted that Section 251 support was initially sought for the 1 year retrospective study only. The CAG requested that the application keep a log of any items of Confidential Patient Information contained in this field. If no items of confidential Patient Information are identified, it would provide evidence that any further follow on study would not require Section 251 support.
2.	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 **25/26** DSPT review for CROWN Informatics Limited, Royal College of Psychiatrists, and Microsoft UK were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 16 October 2026).

1.4	**26/CAG/0086**	**Paediatric Lyme Disease in the United Kingdom and Republic of Ireland**
	Chief Investigator:	Dr Peter J Davis
	Sponsor:	University Hospitals Bristol and Weston NHS Foundation Trust
	Application type:	Research

Present:

Name	*Capacity*
Dr Martin Andrew	Expert CAG Member
Mr Thomas Boby	Expert CAG Member
Professor Lorna Fraser	CAG Chair

Also in attendance:

Name	Position (or reason for attending)
Andrea Bell	Approvals Specialist

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from the University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) is for the purpose of medical research to help identify the number of children with Lyme Disease presenting at hospitals in the UK and

Republic of Ireland. Lyme Disease is not a statutorily notifiable disease, and so, the true incidence of paediatric Lyme Disease in the UK is currently unknown. In order to identify as many cases of Lyme Disease as possible, the researchers aim to collect patient identifiable data without consent from different sources and cross reference the data with Lyme Disease positive laboratory samples.

In undertaking this research, it is hoped that not only the number of incidences of paediatric Lyme Disease in the UK is learned, but the current scientific knowledge about which areas are higher risk for Lyme disease as well as more of an understanding about the symptoms, clinical course and complications of Lyme disease in children, are also further advanced.

The BPSU methodology is established and has received support in principle from the CAG. Paediatricians will report any new patients <16 years of age diagnosed with Lyme disease (either a clinical or laboratory confirmed diagnosis) who presents at hospital. This will be undertaken through the BPSU reporting system via the University of Dundee. The University of Dundee system will generate the initial questionnaire for the reporting clinician to fill in via the University of Dundee data safe haven online platform. The completion of this questionnaire will contain confidential patient information and therefore requires 's251' support. Each case will be given a unique study number by the BPSU study centre. Date of birth, and NHS number will be recorded alongside clinical data on the questionnaires. At 12 months, a follow up will be undertaken via BPSU. All identifiers will be deleted once recruitment is completed, and duplicates identified.

A recommendation for 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential information requested

Cohort	All patients less than 16 years of age diagnosed with Lyme disease (clinical or laboratory confirmed diagnosis) presenting to hospital in the UK and the ROI. The research will include the observational prospective reporting of cases by clinicians over a 13-month period, starting in March 2027 (pending all regulatory approvals are in place). All cases reported will receive a 12 month follow up questionnaire to be completed by the clinician. Cohort size ~ 300
Data Sources	British Paediatric Surveillance Unit (BPSU) • Patient notes

	• Laboratory results • Clinician specific questionnaires Specialist Laboratories in the UK that run diagnostic Lyme disease samples (UK Health Security Agency at Porton Down) • Laboratory case details
Identifiers required for linkage purposes	British Paediatric Surveillance Unit (BPSU) • NHS Number • Date of birth Not CPI • Partial date of birth (month/year) • Sex • Partial postcode • Ethnicity For cases identified via laboratory data • Partial date of birth (month/year) • Partial postcode • Sex • Referring Hospital Lab
Identifiers required for analysis purposes	• Partial date of birth (month/year) • Sex • Partial postcode • Ethnicity

Additional information	Only aggregate results ready for publication will be downloaded from the UoD - HIC safe haven server onto a University Hospitals Bristol and Western NHS Foundation Trust (UHBW) computer.

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	REC Favourable Opinion in place on 19 October 2026.
2.	Security assurances for 2025/26 are outstanding for the following organisations. • University of Dundee Health Informatics Centre (HIC) • UK Health Security Agency (UKHSA) Please contact NHS England at ssd.nationalservicedesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	Security assurances for 2025/26 confirmed for University of Dundee Health Informatics Centre (HIC) Security assurances for 2025/26 DSPT confirmed for UK Health Security Agency (UKHSA)
3.	The CAG request for the following changes to be made to the patient notification materials: a) Circulate the patient notification materials through appropriate channels to ensure they reach all individuals who may be included in	a/b. The applicants explained that they are unable to guarantee circulation to anyone who may be involved

	the study, including those whose laboratory results do not result in an Orange Card notification (for example, where treatment is provided solely by a GP or where a paediatrician does not submit a report). b) It is advised that all materials are circulated using relevant charity websites and other appropriate platforms to improve awareness and visibility of the study amongst the affected patient population.	in the study as theoretically this could be any child in the UK. However, they will ensure the patient notification materials are published through the appropriate professional channels available to them, including the RCPCH and BPSU websites as well as the relevant charities that they have been working with during the development of the study. The CAG noted this and raised no further queries.
	c) Provide a clearer explanation of the project-specific opt-out process. The leaflet should explicitly state that patients and/or their families can object to participation in the study by notifying their treating clinician.	After discussion with the REC team, the applicants decided that the only opt out option for patients would be via the NDDO. The patient information leaflet was updated to reflect this. The CAG noted that the usual process for surveillance studies is for an opt out via the clinician alongside the national data opt out and therefore requested that the t option for parents to contact the clinician if they do not want their data to be included, needed to be reinstated in the leaflet before they could issue support. The leaflet was amended. The revised leaflet was

	d) Clearly explain that NHS numbers will be collected during the initial phase of the study and describe how this information will be used.	reviewed and accepted by the CAG. d. This information has been added to the patient information leaflet. The revised materials were reviewed and accepted by the CAG.

Confidentiality Advisory Group advice: *Fully supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority subject to compliance with the standard conditions of support.

Number	Condition
1.	Favourable opinion from a Research Ethics Committee. **Confirmed 19 October 2026**
2.	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 **25/26** DSPT review for **University of Dundee Health Informatics Centre (HIC) and UK Health Security Agency (UKHSA)** was confirmed as 'Standards Met' on the NHS England DSPT Tracker

1.5	**26/CAG/0081**	**Connected Yorkshire & Humber**
	Chief Investigator:	Dr Michael McCooe
	Sponsor:	Bradford Teaching Hospitals NHS Foundation Trust
	Application type:	Research Database

Present:

Name	Capacity
Mr Dan Roulstone	CAG Vice Chair
Dr Malcolm Booth	CAG Expert Member

Mr Anthony Kane	CAG Lay Member
Dr Pauline Lyseight-Jones	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Dr Paul Mills	Confidentiality Advice Service Manager

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from Bradford Teaching Hospitals NHS Foundation Trust is for the purposes of both medical research to create the Yorkshire and Humber Secure Data Environment (SDE). It is part of the regional SDE network to support the Government initiative of data access by default.

Identifiable health and social care information from a number of sources, including GPs, secondary and community care and social care, will be shared with one of three sub-regional organisations, aligned with the ICBs regions. These sub-regional organisations are Bradford Teaching Hospitals NHS Foundation Trust, University of Sheffield and University of Hull where information will be pseudonymised in each sub-regional organisations using a common pseudonym held by Bradford. Where data for a specific research project is required from multiple sub-regional organisations, the data will be combined and accessed through Bradford Teaching Hospitals NHS Foundation Trust.

Each sub-regional organisation has its own data access committee who will review any request for access to data from that sub-region. Any request that requests data from multiple sub-regions will be considered by a central Yorkshire and Humber SDE data access committee Each data access committee will have a minimum of 30% representation from public representatives.

The application includes provisions to share information in pseudonymised form with other SDEs for multi-SDE projects.

Confidential information requested

Cohort	All patients and services users of all health and care organisation across the Yorkshire and Humber SDE region. This is an estimated population of 5.6 million people
Data sources	• Health and Care organisations within the Yorkshire Humber SDE region, including o Primary care

	○ Acute, Community & Mental Health and Speciality Trusts ○ Ambulance Trusts ○ Local Authority (Social Care data) • NHS England ○ Civil registrations of births and deaths ○ Personal Demographics Service (PDS) ○ Secondary Uses Service (SUS) ○ Community Services Data Set (CSDS) ○ Mental Health Services Data Set (MHSDS) ○ Improving Access to Psychological Therapies (IAPT) ○ Ambulance Data Set (ADS) ○ Adult Social Care Client Level Data (CLD) ○ Social Care – All Age Continuing Care (AACC) ○ e-Referral Service (e-RS) dataset ○ Maternity Services Data Set (MSDS) ○ Medicines Dispensed in Primary Care ○ Diagnostic Imaging Data Set (DIDS) ○ National Cancer Waiting Times Monitoring Data Set (CWT) ○ Alcohol Dependence Data Set ○ Tobacco Dependence Data Set ○ National Diabetes Audit ○ Acorn/UPRN Data
Identifiers required for linkage purposes	• NHS number • Hospital number • Name • Full address • Postcode (unit level) • Date of birth • Date of death
Identifiers required for analysis purposes	• Gender • Ethnicity • Postcode (sector level) Researchers do not require any identifiers for analysis of data during data access arrangements with SDEs.

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place	REC Favourable Opinion now in place
2.	a. Provide a copy of the questions being asked in second survey that is now being conducted. b. Provide an overview of other upcoming public involvement. c. Provide an overview of the public involvement undertaken to date on public views of multi-SDE projects, and the feedback received	This response provided by the applicants was generally accepted, but CAG requested updates on the new survey within 2 months **[Condition 3]**
3.	Submit a copy of the communications plan for review	This was submitted and accepted by CAG, after requests for further updates
4.	The CAG request for the following changes to be made to the patient notification materials: a. Improve information about the use of confidential patient information by making it clearer how confidential patient information will be used. b. Improve information by clearly explaining the use of non-health data such	The applicants updated the patients notification materials, and were further updated after CAG considered that the initial changes still required work. Final versions were accepted, with a condition of support for the poster to have a statement on how to opt out **[Condition 1]**, the leaflet to include a statement on the role of CAG **[Condition 2]**, and to update the website in 6 months **[Condition 4].**

	as social care. c. Explain the local opt-out process for the study d. Describe the role and function of the Confidentiality Advisory Group (CAG) within the study explaining that CAG have reviewed the application and provided advice to the Health Research Authority under section 251 of the NHS Act 2006 e. Include non-electronic contact options for readers to utilise such as a telephone number f. It is advised that the Multi SDE guidance is referred to when making revisions to the patient notification materials, to include information on sharing information between SDEs. g. Present the revised patient notification materials to a public involvement group for feedback	
5.	Confirm that the data already received from an individual who subsequently opts out will not be used for any future or new research.	This was confirmed and accepted by CAG

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	Within 1 month, add a statement to the poster to inform people how to opt out of their data being included in the SDE, with prominence given to the SDE-specific opt out.
2.	Within 1 month, add the following statement to the leaflet "The SDE has gained Section 251 Approval from the Health Research Authority, following advice from the Confidentiality Advisory Group".
3.	Within 2 months, confirm new survey on use of identifiable information has been released, which is explicit on how comfortable respondents are for identifiable patient information to be shared with the SDE, to enable creation of the research database.
4.	Provide an update on progress of the website in 6 months, including addition of information on the types of research undertaken and how identifiable information is used to create the SDE.
5.	Favourable opinion from a Research Ethics Committee. Confirmed
6.	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 25/26 DSPT review for Bradford Teaching Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS England DSPT Tracker

1.6	**26/CAG/0089**	**Development of a novel approach to identify patients at risk of coronary artery disease, using pre-existing longitudinal metabolic biomarkers to correlate with risk of having a high CT coronary calcium score data as a marker of atherosclerotic burden.**
	Chief Investigator:	Dr Timothy Jobson
	Sponsor:	Somerset NHS Foundation Trust
	Application type:	Research

Present:

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Dr Malcolm Booth	CAG Member (Expert)
Mrs Cath Trigwell	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from Somerset NHS Foundation Trust is for the purpose of medical research to work out whether newer, and more powerful ways of analysing pre-existing blood test results can predict which patients are at high risk of Major Adverse Cardiac Events (commonly known as 'heart attacks') by finding patients who have calcium deposits in the arteries in the heart (coronary artery calcium, detected by CT scanning). The applicant aims to develop a novel algorithm using pre-existing routinely collected longitudinal blood test data to identify patients at risk of significant coronary artery disease, as measured by CT coronary calcium score. The hepatoSIGHT® platform, previously validated for liver disease case-finding, will be adapted for this purpose. The hepatoSIGHT® platform has a non-research 's251' support in place, under CAG reference 24/CAG/0074.

Diseases of the heart and blood vessels (collectively known as cardiovascular disease -CVD) and more specifically disease of the main blood vessels in the heart (coronary artery disease – CAD) are a leading global cause of death. It is estimated that 2.3 million people in the UK are living with coronary artery disease which accounts for approximately 66,000 deaths annually. CVD mortality is strongly associated with deprivation and has been shown to be significantly higher in the most deprived areas of England in comparison to the least deprived areas. There is evidence that effective screening for asymptomatic coronary artery disease, leading to earlier secondary prevention approaches, may reduce overall cardiac morbidity and mortality, and therefore a compelling clinical need for a non-invasive, cost-free risk stratification tool that could identify individuals most likely to benefit from CT CAC scoring or more intensive primary prevention. If this research is successful it would mean that clinicians could identify at risk patients for further intervention, without needing to perform additional expensive or burdensome screening tests.

The study requires 's251' support to link a pre-existing database of approximately 10,000 CT coronary calcium scores from various Somerset NHS Foundation Trust cardiology databases with existing longitudinal blood test data held in the hepatoSIGHT® system. Following linkage, all identifying information will be removed, and all subsequent algorithm development will take place on the linked anonymised dataset.

Confidential information requested

Cohort	All adults with at least one CT coronary calcium score recorded in Somerset NHS Foundation Trust cardiology databases, with pre-existing blood test data held in the hepatoSIGHT® system. Target: approximately 10,000 CT CAC record

Data Sources	• Somerset NHS Foundation Trust –
	  ○ hepatoSIGHT® system longitudinal biomarker database
	  ○ cardiology (CT CAC) databases (Order Comms Archive)

Identifiers required for linkage purposes	NHS number only
Identifiers required to be used within hepatoSIGHT®	• Date of birth - used to calculate age at CT CAC score, and year of birth • Postcode - used to derive Index of Multiple Deprivation • date of death – modified to year of death for analysis
Identifiers required for analysis purposes	N/A – analysis is on anonymous data

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	**Action required**	**Response from the applicant**
1.	Security assurances for 2025/26 are outstanding for the following organisation: • Somerset NHS Foundation Trust	This was received on 15 October

	Please contact NHS England at ssd.nationalservicedesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	
2.	The CAG request the following updates in relation to the poster: (a) Include that the processing of confidential patient information without consent is undertaken with 's251' support from the Health Research Authority (HRA), following advice from the Confidentiality Advisory Group (CAG). (b) Add a link or QR code that directs to the privacy notice. (c) The poster should be displayed at all relevant locations for a minimum of a month before the linkage occurs – please confirm that this will happen.	This was updated and CAG were content. The applicant confirmed point 2c.

Confidentiality Advisory Group advice: *Fully supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
1.	Favourable opinion from a Research Ethics Committee. **Confirmed 14 August 2026**
2.	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 **25/26** DSPT review for **Somerset NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker

1.7	**26/CAG/0100**	**Automated Clinical Coding Using Large Language Models**
	Chief Investigator:	Dr Muhammad Faisal
	Sponsor:	University of Bradford
	Application type:	Research

Present:

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair
Ms Kim Keltie	CAG Member (Expert)
Ms Mary Thomas	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application, from University of Bradford, is to investigate whether artificial intelligence (AI), can support or automate aspects of clinical coding within the NHS.

Clinical coding is the process of converting information contained in health records into standardised alphabetical and numeric codes. These codes are important for patient care, hospital planning, research, and NHS funding. This is largely performed manually by trained clinical coders. It is time-consuming and resource intensive due to the increasing volume and complexity of healthcare data.

Relevant patient records from Bradford Teaching Hospitals NHS Foundation Trust will be moved to a separate area within the trust, where large language model (LLM) systems will remove identifiable data items and convert the information into clinical codes. These will be matched with the codes assigned by human coders to test the effectiveness of AI coding. Whilst all information is kept within Bradford Teaching Hospitals NHS Foundation Trust at all times, and it is being deidentified as early as possible, support is requested in case of any potential identifiers remaining in the dataset, as well as for access to the information by researchers at the University of Bradford.

Confidential information requested

Cohort	All patients aged over 18 from Bradford Teaching Hospitals NHS Foundation Trust who received care from 2024 onwards (about 5000 patients)
Data Sources	• Clinical records at Bradford Teaching Hospitals NHS Foundation Trust
Identifiers required for preparation and validation of the dataset	• Hospital ID and/or NHS number. • Free text records will be deidentified as soon as possible by automated means, but will be treated as potentially identifiable.
Identifiers required for analysis purposes	None
Additional information	Clinical records will include discharge summaries, relevant clinical notes, principal diagnoses, comorbidities, hospital course, procedures, and ICD-10 codes already assigned by professional clinical coders

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	Security assurances for 2025/26 are outstanding for the following organisations: • Bradford Teaching Hospitals NHS Foundation Trust Please contact NHS England at ssd.nationalservicedesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	Confirmed 02 October 2026.
2.	The CAG request that further consideration should be given to location of the notification materials. These materials should be presented in appropriate clinical settings including wards outpatients and the Trust website.	Further consideration has been given to the location of the patient notification materials. Posters will be displayed in appropriate clinical areas across Bradford Teaching Hospitals NHS Foundation Trust, including

		relevant inpatient wards and outpatient areas. A dedicated study webpage will be created on the Improvement Academy website; is part of the Bradford Institute for Health Research hosted within the NHS by Bradford Teaching Hospitals NHS Foundation Trust. The Improvement Academy already hosts similar public facing information for LLM-related research, Use of LLMs in Research" webpage: https://improvementacademy.org/use-of-llms-in-research/ A similar page will be created for this study and will provide information about the purpose of the research, how patient information will be used and protected, the use of the LLM, the specific project opt-out, the National Data Opt-Out, and contact details for the study team.
3.	The CAG request the following changes to the poster: a) At the top of the poster, include introductory text to clearly state that this is a research project, and also state who this applies to (for example, but using such wording as "if you were a patient between [x periods of time], this project may apply to you". b) Change the order of the opt out information so that the project specific opt out is first, followed then by the National Data Opt Out information.	1. Introductory text has been added at the top of the poster to make clear that this is a research project and to explain who the study may apply to. The poster now states that the research may apply to adults aged 18 years above who received inpatient care at Bradford Teaching Hospitals NHS Foundation Trust between 2024 and 2026. 2. The opt-out information has been reordered so that the project opt-out is presented first, followed by information about the NHS National Data Opt-Out.

	c) The title needs to explain that this is research, e.g. Research study: Using AI to support…' d) The opt-out box at the top can be removed, as the information is given further down. e) In 'Why are we doing this research', include the potential benefits of the study, such as improvements to patient care.	3. The title has been revised to make clear that this is research and now reads: "Research study: Using AI to support clinical coding in NHS hospitals." 4. The opt-out box previously displayed at the top of the poster has been removed, as the opt-out information is provided in the dedicated section further down the poster. 5. The "Why are we doing this research?" section has been revised to include the potential benefits of the study, including supporting more complete and accurate clinical coding and helping hospitals to better understand, plan and improve patient care.

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	The CAG stated that support for the project only covers ICD-10 codes. A modification will need to be submitted if the project intends to expand to also include ICD-11 codes in the future.
2.	Favourable opinion from a Research Ethics Committee. **Confirmed 14 September 2026.**
3.	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 **2025/26** DSPT review for Bradford Teaching Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 27 October 2026).

1.8	**26/CAG/0108**	**Service Evaluation for Newborn screening for Spinal Muscular Atrophy (SENS)**
	Chief Investigator:	Professor Laurent Servais
	Sponsor:	University of Oxford
	Application type:	Research

Present:

Name	Capacity
Professor Ben Gibbison	CAG Alternate Vice Chair
Dr Malcolm Booth	CAG Member (Expert)
Dr Pauline Lyseight-Jones	CAG Member (Lay)
Dr Justin Yang	CAG Member (Expert)

Also in attendance:

Name	Position (or reason for attending)
Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from University of Oxford is for the purpose of medical research to evaluate the effectiveness of the newborn screening program for spinal muscular atrophy (SMA).

SMA is a disease that causes progressive muscle weakness. There are many types- the most severe and most common, type 1, affects very young babies, and is life-threatening if untreated. Other types can cause significant disability. Three new treatments can slow or prevent symptoms, but they work best when given before symptoms appear. This has led to many countries introducing newborn screening (NBS) for SMA, so that affected babies can be treated as early as possible.

A UK pilot project screened nearly 33,000 babies and found the test to be accurate and practical, but this pilot was too small to show whether screening improves outcomes or is good value for money for the NHS. The UK National Screening Committee would also like to know how acceptable NBS for SMA is for different

groups of people. This new study is designed to answer those questions.

's251' support is required for confidential patient information (full date of birth for all screened, and NHS number for positive cases) from screened babies to be disclosed from the newborn screening laboratories to STRONG, based at University of Oxford, to allow the full evaluation to be completed.

Confidential information requested

Cohort	All newborn babies who are born from 1 October 2026 until September 2030 and are screened for standard NHS NBS at the seven designated screening centres (positive and negative data), about 755,000 in total
Data Sources	• 7 newborn screening laboratories: o Manchester University NHS foundation Trust o Epsom and St Helier University Hospitals NHS trust o Birmingham Woman's and Children's NHS foundation trust o Sheffield Children's Hospital o Great Ormond Street Hospital o Royal Victoria Infirmary Newcastle upon Tyne o Guys and St Thomas's NHS foundation trust
Identifiers required for linkage purposes	1. All screened babies: Date of birth, ethnicity. 2. NHS number & sex in addition for positive cases
Identifiers required for analysis purposes	• Full date of birth
Additional information	University of Oxford will receive the data from the labs on a monthly basis.

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence

Number	Action required	Response from the applicant
1.	Provide details of multiple accessible routes that will be used in this study for patients to opt out of data being included.	The applicant has now included multiples ways to opt out on all the various notification documents and CAG were content with this.

2.	Provide a copy of the revised patient notification materials. The revised materials should also include: a) Ensure that multiple routes to opt out of the specific study are described, with prominence to the study specific opt out. b) State that the national data opt out will be applied. c) State that the study has received Section 251 support from the Health Research Authority, following advice from the Confidentiality Advisory Group. d) Ensure that all information is presented in clear, accessible language that is readily understood by the target patient population, for example, by review from a public involvement group	Revised materials were provided. The information has been reviewed by STRONG PPI group, consisting of parents who children have SMA (6 members) with the feedback being the information was clear, the tone was appropriate and they understood how to opt out. Materials are currently under a wider review with several larger PPI groups including two local national maternity Voices groups (general public with interest in maternity services), the University of Oxford's Department of Paediatrics' PPI group (~60 members) and the research study PPI group (run by our collaborator at University of Warwick and King College London, ~20 members including families with SMA, general public and health professionals). Applicants expect to receive this feedback shortly. CAG would like to see this feedback from the PPI groups when it is available (**Condition 2).** The CAG requested various updates to the provided notification materials as detailed in **Condition 1.** This is due to various errors in spelling, grammar, and layout– for example; • The address for the opt-out on the website contains the typo "corridoor" • The final two paragraphs of the website wording is slightly ambiguous about whom this study applies (i.e. how will I know if my baby is being screened for SMA and whether this applies to me?) • The word "however" should be removed from: "However, **I**f you do not wish for your baby's data to be shared with the research team for the purpose of the study, you are free to opt out."

		"However" here might seem to imply it is exceptional for someone to want to remove their baby from the study. • Consider emboldening or adding subheadings to make clear the information about national and project-specific opt out. • Consider breaking up the second paragraph to make the text more inviting and less dense to read.
3.	Provide a copy of the study communication plan. It should clearly demonstrate how the study will inform patients and the wider public about the use of confidential patient information without explicit consent, including the key messages, communication methods	This was provided. The Members felt that the communication plan is currently very vague and generic. CAG requested this be updated with more concrete information about "the how" the applicant plans to communicate this to the public - which platforms will be used, and will there be video's, audios, local radio adverts, for example. It should also be re-read and amended (typos and spelling), including "adverting material" and "lager groups". **(Condition 3)**

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	With regards to all notification documentation, the following updates should be completed, and provide updated versions to CAG in one month; a) Read and correct all of the multiple grammatical and spelling errors throughout the all the documents. b) The QR codes on the poster are too close together - they should be at least 4cm square, with 2-3cm apart to allow them to be easily distinguishable. c) The wording on the website and elsewhere about the NDOO needs to be in plain English: "*We will apply the*

	national opt out scheme to this data" should read something like "*If you have opted out of having your data used as part of the National Data Opt Out, we will not use your information in this study and you need do nothing further*". d) Ensure a public involvement participant has reviewed all updated materials, specifically seeking advice regarding how to break up the text to make it accessible.
2.	CAG would like to see the further Public involvement feedback from Warwick and Kings College when available.
3.	The communication "plan" is currently very vague and generic. Please can this be updated with more concrete information about "the how" you plan to communicate this to the public - which platforms you will use, and will there be video's, audios, local radio adverts, for example. Please provide this updated plan within one month.
4.	Undertake further patient and public involvement throughout the duration of the study to ensure ongoing engagement regarding the use of confidential patient information. Please feed this back at annual review. It is advised that during these activities should include discussions on the following below: a) how confidential patient information is being used, the rationale for its use, b) an overview of the study's progress, potential modifications or additional requirements
5.	Favourable opinion from a Research Ethics Committee. **Confirmed: Original REC Favourable Opinion in place on 29 June 2026, with confirmation conditions met 2 July. However, with regards to the addition of CAG, a modification was given Favourable opinion on 08 October 2026**
6.	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:** Due to the number of organisations involved it is the responsibility of University of Oxford as controller, to ensure that organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

1.9	**26/CAG/0098**	**Identifying core components of care transitions from specialist palliative care to primary care – recommendations for improving hospital discharge communications: a Delphi and rapid ethnography study**
	Chief Investigator:	Dr Katharine Weetman
	Sponsor:	University of Birmingham
	Application type:	Research

Present:

Name	Capacity
Mr Dan Roulstone	CAG Vice Chair
Dr Joanne Bailey	CAG Member (Expert)
Mr Anthony Kane	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the request for further information in correspondence.

Summary of application

This application from University of Birmingham is for the purpose of medical research to identify barriers to discharge from specialist palliative care to community settings and further develop recommendations for improving hospital discharge communication.

People with life-limiting and serious illnesses are often discharged from hospital, though they may need support again later. A smooth transfer of care is important to make sure it continues without disruption. Otherwise, patients, their families and carers can get confused, upset and perhaps have pain or other problems especially if they have not got the right information. In the worst cases, patients may have to come back to hospital. Therefore, facilitating clear, accurate, and timely discharge care handover and co-ordination between specialist palliative care and primary care is essential. Palliative care discharges are a priority, so it is important to improve the quality and content of these hospital processes and communications. Currently, little is known about how these discharge communications affect patients' and carers' experiences or what their communication needs are at this critical moment in their lives.

Researchers are undertaking a number of different work packages with different methodologies to answer the research question, including consented staff

observations and interviews. These elements do not require ‘s251’ support.

However, the researchers, who are not considered direct care team, are also undertaking ethnographic observations, including observing clinical practice and communications of specialist palliative care teams (including all staff roles associated with these discharges) and ward rounds and other clinical discussions/practice with palliative care patients (e.g. oncology, cardiology etc.) as well as staff interactions, meetings and discussions (e.g. Multi-Disciplinary Team (MDT) meetings to observe discharge discussions). The observations will focus on clinical practice and communications of specialist palliative care teams, not on individual patients or clinical outcomes. Support under Regulation 5 is required for this aspect of the study, as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded. Observations are anticipated to take place around 4 weeks per site (approx. 20 days at each site and therefore 60 days total). The researcher may attend around 3 MDT meetings per week at each site, and ~15-20 patients may be discussed per MDT.

Confidential information requested

Cohort	Adult patients who have recently been discharged, or are pending/been identified for discharge from NHS hospital specialist palliative care, who are discussed during observations of clinical practice and communications of specialist palliative care. This is estimated to be approximately 750 patients, as observations are anticipated to take place around 4 weeks per site (approx. 20 days at each site and 60 total). The researcher may attend around 3 MDT meetings per week and ~15-20 patients may be discussed per MDT.
Data Sources	MDTs and other clinical areas at NHS sites - University Hospitals Birmingham, South Warwickshire Foundation Trust, and University Hospitals Coventry and Warwickshire.
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes (without consent)

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant’s response to the request for

further information in correspondence

Number	Action required	Response from the applicant
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	This was confirmed on 13 October.
2.	Security assurances for 2025/26 are outstanding for the following organisations. • University Hospitals Birmingham • South Warwickshire Foundation Trust • University Hospitals Coventry and Warwickshire Please contact NHS England at ssd.nationalservicedesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	These were provided.
3.	Update the data flow diagram to clearly identify all data flows involving the disclosure of confidential patient information. The data flow diagram should highlight where there might be an incidental flow.	Overall CAG were content with the data flow diagram, however a condition has been added to provide an updated data flow diagram (DFD) regarding the 's251' supported elements. Although the data items and data controllers are clear, the DFD refers to common law bases of consent and public interest. The common law basis for processing of confidential patient information without consent with regards to the observations will be s251 not public interest. Noting it is difficult to describe all of the different processes on one DFD, CAG would prefer that the applicant provide a DFD regarding the observations, for clarity.
4.	The CAG request for the following changes to be made to the patient notification leaflet:	These were updated and CAG were content with the changes made.

	a) Provide information explaining that incidental exposure to communications would not form part of the opt-out process. b) Provide details of the study digitally via a webpage. c) Include a statement explaining that Section 251 support has been provided by the HRA following CAG advice.	

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	Please provide an updated data flow diagram (DFD) just regarding the 's251' supported elements, within 1 month. Although the data items and data controllers are clear, the DFD refers to common law bases of consent and public interest. The common law basis for processing of confidential patient information without consent with regards to the observations will be s251 not public interest (it would be 's251' support). Noting it is difficult to describe all of your different processes on one DFD, CAG would prefer you split it up and provide us just the DFD regarding the observations. Please colour code or add a label on the incidental disclosure element to indicate that this is under 'S251' as the common law legal basis for processing.
2.	Favourable opinion from a Research Ethics Committee. **Confirmed 13 October 2026**
3.	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 **25/26** DSPT reviews for **University Hospitals Birmingham, South Warwickshire Foundation Trust & University Hospitals Coventry and Warwickshire** were confirmed as 'Standards Met' on the NHS England DSPT Tracker

2. Response to CAG conditions

At times, the CAG may set specific conditions for an application to meet, and report back to CAG. These application specific conditions are generally reviewed by the sub-committee of reviewers, unless otherwise stated.

Each response to condition that has been confirmed by CAG as being met in the month is listed below, as well as any remaining outstanding conditions for that application.

2.1	**26/CAG/0063**	**Using Large Language Models (LLMs) to review hospital data to improve safety across the patient journey**
	Chief Investigator:	Professor Tom Lawton
	Sponsor:	Bradford Teaching Hospitals NHS Foundation Trust
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

A Sub-Committee of the CAG considered the applicant's response to the conditions in correspondence.

The following conditions have been confirmed as being met:

Number	Condition
1.	The text on the website needs to be revised to state that the CAG recommended support, rather than gave support. Please provide the revised text within one month of the sending of this letter. **Condition met 08 October 2026.**
2.	Favourable opinion from a Research Ethics Committee. **16 April 2026.**
3.	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 2024/25 DSPT review for Bradford Teaching Hospitals NHS Foundation Trust was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 July 2026).

3. New modifications

The review route of modifications will depend on how substantial the modification is and will be determined according to Standard Operating Procedures. It can be any one of the Confidentiality Advice Team, CAG Officer, CAG sub-committee or full meeting of the CAG.

Each modification below will state the advice route a modification has been through before confirming the outcome with the Decision Maker.

3.1	**22/CAG/0026**	**Covid impact on RSV Emergency Presentations: BronchStart**
	Chief Investigator:	Professor Damian Roland
	Sponsor:	University Hospitals of Leicester NHS Foundation Trust
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

The Confidentiality Advice Team reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

This application by the University Hospitals of Leicester NHS Trust sought to understand the impact of the re-emergence of respiratory syncytial virus (RSV) on the rate of bronchiolitis in those under 2 years of age.

The applicants have existing support to allow research nurses, who are not part of the direct care team, to access confidential patient information held in medical records for children under two years of age presenting to participating emergency departments with clinical features of bronchiolitis, acute lower respiratory tract infection or first episode of wheeze, to extract an anonymised dataset for input into the REDCap database.

In this request, the applicants seek to expand the data collection to include data on vaccinated patients admitted to hospital, with the aim of calculating vaccine effectiveness. To support this, the applicants also seek to collect patients hospital numbers, to assess whether patients are admitted multiple times.

Confidentiality Advisory Group advice: *Fully supported*

The Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
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: Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 September 2026.**

3.2	**23/CAG/0010**	**The SHIPS Study: Sharing Information at the Primary / Secondary care interface – improving patient care by ensuring that GPs get the information they need when someone is discharged from hospital**
	Chief Investigator:	Dr Lucy Pocock
	Sponsor:	University of Bristol
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

The Confidentiality Advice Team reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

The applicants have existing support to allow for incidental exposures of confidential patient information that may occur when the researcher is undertaking observations

of multidisciplinary team meetings, board round meetings, interactions between HCPs and observations of clinicians preparing discharge communications about patients on the ward,

In this request, the applicants seek to include Leeds Teaching Hospitals NHS Trust (LTHT) as an additional site. The applicants also seek to extend the duration of support from 1 October 2026 to 31 March 2027, to allow time for the observations to take place at LTHT.

Confidentiality Advisory Group advice: *Fully supported*

The Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
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 2025/26 DSPT review for Leeds Teaching Hospitals NHS Trust was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked **28 September 2026**).
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 01 September 2026.**

3.3	**21/CAG/0060**	**A pan cancer programme of tumour typing (version 1)**
	Chief Investigator:	Dr Nicolas Orsi
	Sponsor:	Leeds Teaching Hospitals NHS Trust
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

The Confidentiality Advice Team reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

The applicants have existing support to allow members of staff at Leeds Teaching Hospitals NHS Foundation Trust, who are not members of the direct care team, to access confidential patient information held in electronic patient records at the Trust in order to link information from the more than one source within the hospital site and identify archival tissue samples.

In this request, the applicants seek to expand the scale of the study. These changes include:

- Extending the duration of support until 05 June 2033.
- Increasing the cohort size from 12,000 to 29,000.
- Changing the focus of the study to concentrate on rarer cancer indications and treatment-resistant cancers.

These changes are driven by developments in cancer treatment and management since the study began, including wider use of immunotherapies, antibody-drug conjugates, and molecularly targeted therapies. The larger cohorts are needed to capture these more diverse treatments and the increased granularity of data. The study protocol has been updated to reflect the changes made.

The applicants also noted that new staff had joined the research team and that additional tissue processing sites had been added. However, these revisions do not impact on the scope of support under s251.

Confidentiality Advisory Group advice: *Fully supported*

The Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
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 2025/26 DSPT review for Leeds Teaching Hospitals NHS Trust was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 02 October 2026).
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 October 2026.**

3.4	**23/CAG/0135**	**VIVALDI Social Care**
	Contact:	Professor Laura Shallcross
	Data controller:	University College London
	Application type:	Non-research

Also in attendance:

Name	Position (or reason for attending)
Kathleen Cassidy	Confidentiality Advisor

The Confidentiality Advice Team reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

This non-research database includes data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. 's251' support is in place to collect data from at least 500 homes and up to 30,000 residents in England, and link these data with outcome data.

In this request, the applicants seek to extend the study end date from 31 October 2026 to 31 December 2027. The extension is needed due to delays in establishing data flows and activating participating care homes. This meant that data collection began later than originally anticipated.

The patient notification materials have also been updated with the new end date.

Confidentiality Advisory Group advice: *Fully supported*

The Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the standard conditions of support.

Number	Condition
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 2025/26 DSPT review for **NHS England & Arden and GEM Commissioning Support Unit** was confirmed as 'Standards Met' on the NHS England DSPT Tracker Due to the number of care providers and/or software vendor organisations involved, it is the responsibility of University College

	London, as controller, to ensure that processing organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.

3.5	**24/CAG/0061**	**Barrett's oESophagus Trial 4 (BEST4): A Randomised Control Trial Comparing capsule sponge Test Screening to Usual Care**
	Chief Investigator:	Professor Rebecca Fitzgerald
	Sponsor:	University of Cambridge
	Application type:	Research

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair

Also in attendance:

Name	Position (or reason for attending)
Caroline Watchurst	Confidentiality Advisor

A CAG Officer reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

The BEST4 Screening trial is a Randomised Control Trial (RCT) comparing capsule sponge test screening to usual care. The applicants have 's251' support to contact patients in England via NHS DigiTrials to seek consent. Specifically 's251' support is in place to allow the disclosure of confidential patient information from NHS England to iPlato Ltd, the contracted SMS supplier, to facilitate the sending of invitation SMS, and invitation advertisement through the myGP app. 's251' support is not required for the processing of confidential patient information by NHS England employees to generate the cohort to be invited into the research programme, as this is covered by Directions (specifically the Pilot NHS DigiTrials Recruitment Support Services Direction 2021, (and amendment 2 (2023) which extends the number of trials, and length of time) Pilot NHS DigiTrials Recruitment Support Services Directions 2021 - NHS England Digital).

A previous modification has been supported to increase the number of invites sent from 4.5 million to 8 million. 10 million invites were requested at the time, however the CAG Chair was content to support 8 million, based on calculations the applicant provided.

This modification sought support to increase the number of individuals invited to 8.5 million, from 8 million, as based on the current data for the trial, it has been calculated that an additional 0.5 million invites will be necessary to continue inviting participants until end of December 2026.

This modification also sought support to remove Datagraphic as a data processor. The applicant has confirmed that any reminders will now be sent by NHS Notify only.

The amendment also informed CAG of 2 additional sub-processors of iPlato - Sinch and Huma Therapeutics. Assurance is provided through a combination of:
• Contractual data protection and security commitments
• Independently certified security frameworks (e.g. ISO 27001)
• NHS-accepted equivalence routes for non-NHS suppliers
This is consistent with NHS England guidance for cloud and telecoms providers where
DSPT registration is not applicable, and aligns with previously supported modification to CAG.

Confidentiality Advisory Group advice: *Fully supported*

The CAG Officer agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
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 **25/26** DSPT reviews for **iPlato Ltd, Amazon Web Services & NHS Notify (covered by NHS England)**, were confirmed as 'Standards Met' on the NHS England DSPT Tracker And the Welsh IG toolkit team WIGTK review for **Digital Health and Care Wales** was confirmed as 'Expectations Exceeded' on the Welsh IG toolkit team WIGTK Tracker
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 27 November 2025 (10 million invites already supported by REC in 2025 so no new modification required).**

3.6	**24/CAG/0013**	**Wessex Secure Data Environment**
	Chief Investigator:	Professor Christopher Kipps
	Sponsor:	University Hospital Southampton NHS Foundation Trust
	Application type:	Research Database

Present:

Name	Capacity
Dr Ben Gibbison	CAG Alternate Vice Chair
Dr Joanne Bailey	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Pauline Lyseight-Jones	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Dr Paul Mills	HRA Confidentiality Advice Service Manager

A Sub-Committee of the CAG reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

This Wessex Secure Data Environment (SDE) currently has Section 251 support for all NHS primary and secondary care organisations within the Wessex SDE footprint to share confidential patient information with University Hospital Southampton NHS Foundation Trust for linkage and retention within the SDE environment.

The initial support allowed SDEs to operate in silos, that is to collect confidential patient information from their SDE area to link and deidentify ready for access by researchers. However, many research projects may span multiple SDE areas due to either the nature of the research or the care pathway. This modification requested support for Wessex SDE to process confidential patient information to enable sharing of pseudonymised information with other SDEs for multi-SDE projects. It also enables Wessex SDE to act as the 'Prime' (lead) SDE, whereby other SDEs will share pseudonymised information to Wessex SDE.

The modification does not cover sharing of confidential patient information between SDEs.

Confidentiality Advisory Group advice: *Conditionally supported*

A sub-committee of the CAG considered the modification in principle was content to support. Whilst members noted that, in the future, SDEs may use federation to not share information at all, this is not yet an option.

As such, CAG focussed on ensuring that the materials used to inform the Wessex population were transparent in how pseudonymised information may be shared between SDEs, and that public involvement has been undertaken to inform how SDEs undertake multi-SDE projects. Members agreed that the information was

sufficiently clear but noted that the use of local authority information was not included. All notification materials should be updated with one month to make reference of local authority data. **[Condition 1].**

CAG noted that the SDE has undertaken some public involvement relating to multi-SDE projects and were content to provide support to this modification on this basis. CAG also noted that public involvement should be ongoing and noted further plans to undertake this. Members asked for an update on this in April 2027. **[Condition 2]**.

The CAG sub-committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	Within one month, provide updated notification materials that include reference to Local Authority data.
2.	Provide an update on further public involvement the SDE has undertaken, including n multi-SDE projects by April 2027
3.	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 25/26 DSPT reviews for University Hospital Southampton NHS Foundation Trust, University of Southampton - Clinical Informatics Research Unit (CIRU), & ARROW BUSINESS COMMUNICATIONS LIMITED (TRADING UNDER BRAND NAME ARO were confirmed as 'Standards Met' on the NHS England DSPT Tracker Due to the number of other participating organisations involved it is the responsibility of University Hospital Southampton NHS Foundation Trust, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised
4.	Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed

3.7	**24/CAG/0013**	**Wessex Secure Data Environment**
	Chief Investigator:	Professor Christopher Kipps
	Sponsor:	University Hospital Southampton NHS Foundation Trust
	Application type:	Research Database

Present:

Name	Capacity
Dr Ben Gibbison	CAG Alternate Vice Chair
Dr Joanne Bailey	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Pauline Lyseight-Jones	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Dr Paul Mills	HRA Confidentiality Advice Service Manager

A Sub-Committee of the CAG reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

This Wessex Secure Data Environment (SDE) currently has Section 251 support for all NHS primary and secondary care organisations within the Wessex SDE footprint to share confidential patient information with University Hospital Southampton NHS Foundation Trust for linkage and retention within the SDE environment.

This modification requested access to local authority data, based on the needs of a project and agreed by the data access committee. Local authority data transferred to the SDE may include social care, public health, environment, education (including school census), children's services, housing, home services (physio/occupational therapy, speech & language therapy, dietetics, home nursing, residential care, drug & alcohol support, memory clinics) etc, depending on specific project needs.

Confidentiality Advisory Group advice: *Conditionally supported*

A sub-committee of the CAG considered the modification and were content to support. It was noted that the use of local authority information was not included on notification materials. All notification materials should be updated with one month to make reference to local authority data. **[Condition 1].**

The CAG sub-committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition

1.	Within one month, provide updated notification materials that include reference to Local Authority data.
2.	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 25/26 DSPT reviews for University Hospital Southampton NHS Foundation Trust, University of Southampton - Clinical Informatics Research Unit (CIRU), & ARROW BUSINESS COMMUNICATIONS LIMITED (TRADING UNDER BRAND NAME ARO were confirmed as 'Standards Met' on the NHS England DSPT Tracker Due to the number of other participating organisations involved it is the responsibility of University Hospital Southampton NHS Foundation Trust, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised
3.	Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed

3.8	**24/CAG/0025**	**West Midlands Secure Data Environment**
	Chief Investigator:	Professor Simon Ball
	Sponsor:	University Hospitals Birmingham NHS Foundation Trust
	Application type:	Research Database

Present:

Name	Capacity
Dr Ben Gibbison	CAG Alternate Vice Chair
Dr Joanne Bailey	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Dr Pauline Lyseight-Jones	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Dr Paul Mills	HRA Confidentiality Advice Service Manager

A Sub-Committee of the CAG reviewed the above modification in line with the CAG

considerations in correspondence.

Summary of modification request

This West Midlands Secure Data Environment (SDE) currently has Section 251 support for all NHS primary and secondary care organisations within the West Midlands SDE footprint to share confidential patient information with University Hospitals Birmingham NHS Foundation Trust for linkage and retention within the SDE environment.

The initial support allowed SDEs to operate in silos, that is to collect confidential patient information from their SDE area to link and deidentify ready for access by researchers. However, many research projects may span multiple SDE areas due to either the nature of the research or the care pathway. This modification requested support for West Midlands SDE to process confidential patient information to enable sharing of pseudonymised information with other SDEs for multi-SDE projects. It also enables West Midlands SDE to act as the 'Prime' (lead) SDE, whereby other SDEs will share pseudonymised information to West Midlands SDE.

The modification does not cover sharing of confidential patient information between SDEs.

Confidentiality Advisory Group advice: *Conditionally supported*

A sub-committee of the CAG considered the modification in principle was content to support. Whilst members noted that, in the future, SDEs may use federation to not share information at all, this is not yet an option.

As such, CAG focussed on ensuring that the materials used to inform the West Midlands population were transparent in how pseudonymised information may be shared between SDEs, and that public involvement has been undertaken to inform how SDEs undertake multi-SDE projects

CAG agreed that the majority of the content of the poster and leaflet were satisfactory. However it was felt that the poster in particular could benefit for increased transparency on what identifiable data items are shared with the SDE, as well as how to find more information. The level of information on the poster could be balanced against removing much of the first paragraph, and well as removing the reference to CAG. **[Condition 1].** In addition, the leaflet would benefit from more information on how identifiable information flows to the SDE, and how it is then used to support creation of the final dataset. **[Condition 2].**

CAG noted that the SDE has undertaken some public involvement relating to multi-SDE projects and were content to provide support to this modification on this basis. CAG also noted that public involvement should be ongoing and noted further plans to undertake this. Members asked for an update on this in April 2027. **[Condition 3].**

Members noted the intention to update the website, and requested that information on the types of research undertaken and how identifiable information is used to

create the SDE is added. An update on progress was requested in 6 months. **[Condition 4].**
The CAG sub-committee agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition
1.	Within one month of support being issued, provide an updated version of the poster with the following: a. A reference on how to find further information b. Provide examples of the type of identifiable data items (e.g. name / NHS number) that are shared with the SDE. c. Consider removing some of the details of the poster as it contains lots of information. For example, consider reducing the first paragraph. d. The section referencing CAG can be removed.
2.	Within one month of support being issues, provide an updated version of the leaflet with the following: a. In Plain English, add detail on how identifiable information flows to the SDE and how the SDE uses this to create the SDE.
3.	Provide an update on further public involvement the SDE has undertaken, including n multi-SDE projects by April 2027
4.	Provide an update on progress of the website in 6 months, including addition of information on the types of research undertaken and how identifiable information is used to create the SDE.
5.	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 25/26 DSPT reviews for University Hospitals Birmingham NHS Foundation Trust & NHS England were confirmed as 'Standards Met' on the NHS England DSPT Tracker Due to the number of other participating organisations involved it is the responsibility of University Hospitals Birmingham NHS Foundation Trust, as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any

	concerns are raised
6.	Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed

3.9	**23/CAG/0134**	**VIVALDI Social Care Database**
	Chief Investigator:	Professor Laura Shallcross
	Sponsor:	University College London
	Application type:	Research Database

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	Confidentiality Advisor

The Confidentiality Advice Team reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

This research database includes data on infections, hospital attendances, vaccinations, antibiotic prescriptions, and deaths in older adults who live in care homes. ‘s251’ support is in place to collect data from at least 500 homes and up to 30,000 residents in England, and link these data with outcome data.

In this request, the applicants seek to extend the study end date from 31 October 2026 to 31 December 2027. The extension is needed due to delays in establishing data flows and activating participating care homes. This meant that data collection began later than originally anticipated.

The patient notification materials have also been updated with the new end date.

Confidentiality Advisory Group advice: *Fully supported*

The Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
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 2025/26 DSPT review for **NHS England & Arden and GEM Commissioning Support Unit** was confirmed as 'Standards Met' on the NHS England DSPT Tracker Due to the number of care providers and/or software vendor organisations involved, it is the responsibility of University College London, as controller, to ensure that processing organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation.
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 September 2026**

3.10	**23/CAG/0182**	**Suicide crisis and self-harm attendance at A&E in autistic children and young people**
	Chief Investigator:	Dr Pooja Saini
	Sponsor:	Liverpool John Moores University
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor

The Confidentiality Advice Team reviewed the above modification in line with the CAG considerations in correspondence.

Summary of modification request

The applicants have existing support to allow a named researcher, who is not part of the direct care team, to view confidential patient information at 6 participating A&E sites, whilst undertaking screening for eligibility, in order to extract an effectively anonymised dataset for analysis.

In this request, the applicants seek to extend the duration of support until 30 April 2027.

The researchers have experienced delays when undertaking the data collection. The additional time will allow the PhD student to complete their project.

This modification also removes Greater Manchester Mental Health NHS Foundation Trust (re Royal Manchester Children's Hospital & North Manchester General) & Cheshire and Wirral Partnership NHS Foundation Trust (re Arrowe Park & Countess of Chester Hospital) from 's251' support, as the 's251' supported research is only being undertaken now at Alder Hey.

Confidentiality Advisory Group advice: *Fully supported*

The Confidentiality Advice Team agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support.

Number	Condition
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 2025/26 DSPT review for **Alder Hey NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-substantial on 25 August 2026.**

4. Annual reviews supported

Unless otherwise stated in the comments column, Annual reviews are reviewed by the Confidentiality Advice Team.

CAG reference	Title	Comments
24/CAG/0121	Intensive Care National Audit & Research Centre (ICNARC) Case Mix Programme (CMP)	
25/CAG/0002	Data linkage to understand the factors influencing equity and outcomes of genetic testing across the Welsh population	Annual review reviewed by CAG Officer (Dr Murat Soncul)
15/CAG/0158	Fracture Liaison Service Database (FLS-DB)	
25/CAG/0077	WeLL-Bradford study	
23/CAG/0094	INSIGHT-2: Mechanistic Studies into Pregnancy Complications and their Impact on Maternal and Child Health	

23/CAG/0121	Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries (BE SURE)	

5. End closure activities

Below lists all applications that have submitted an end closure report to CAG and no longer rely on Regulation 5 support. Therefore, a common law legal basis for their activity is no longer required and in effect.

CAG reference	Title
24/CAG/0125	Fostering tEAmwork for ResiLiEnt Staff and Safe care: driving post-pandemic recovery and renewal in Intensive Care Units
24/CAG/0044	i-SAMPLE
25/CAG/0139	2025 Adult Inpatient Survey
25/CAG/0073	Brain Injury outcomes using Routine Data and Imaging analysis (BIRDI)
24/CAG/0131	Protect-C: Population Based Germline Testing for Early Detection and Prevention of Cancer
22/CAG/0064	Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries (BE SURE)

Record of Activity ratified in correspondence from

Professor Lorna Fraser, CAG Chair, Mr Dan Roulstone, CAG Vice-Chair, Professor William Bernal & Professor Ben Gibbison, CAG Alternate Vice-Chairs *11 November 2026*

…… ……..
Signed – Chairs *Date*

Ms Caroline Watchurst *04 November 2026*
…… ……..
Signed – Confidentiality Advisor *Date*