Monthly record of activity of the Confidentiality Advisory Group

September 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/0024**	**Retrospective secondary data analysis of the Outcomes for children and young people referred to a National Gender Identity Development Service between 2009 – 2020**
	Chief Investigator:	Dr Edward Kendall
	Sponsor:	NHS England

	Application type:	Research

Present:

Name	Capacity
Dr Martin Andrew	CAG Member - Expert
Dr Malcolm Booth	CAG Member - Expert
Professor Ben Gibbison	Alternate Vice Chair
Dr Pauline Lyseight-jones	CAG Member - Lay

Also in attendance:

Name	Position (or reason for attending)
Dr Paul Mills	HRA 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 NHS England is for the purpose of medical research to increase understanding of the needs, clinical management and outcomes of young people referred to the former Gender Identity Development Service (GIDS) between 2009 – 2020.

Some children and young people can experience significant levels of gender-related distress during their development, arising from a persistent mismatch between a young person's gender identity and the sex they were registered/assigned at birth. The number of children and young people previously referred to the Tavistock and Portman's Gender Identity Development Service (GIDS) rose over a decade. There were also changes in the group of young people referred, including an increase in birth-registered females being referred and a high representation of young people who have traits or a diagnosis of autistic spectrum condition. To improve the planning and design of NHS services, as well as clinical decision-making for and with patients, the applicants seek to use medium and long term outcome data. The applicants also want to better understand the needs of this changing population, identify the management options offered and assess outcomes for children and young people who have experienced gender related distress.

The study will be undertaken in two phases. In phase 1, clinical information of the population from the Tavistock and Portman NHS Foundation Trust Gender Identity Development Service (GIDS) will be extracted and then linked to a range of national datasets at NHS England. In phase 2, NHS England will share cohort identifiers with the Adult Gender Identity Clinics (GICs) who will return relevant clinical information to NHS England for linkage. The final dataset will be held in the NHS England

Secure Data Environment for analysis. A modified linkage process will be used, using postcode and date of birth to identify the NHS numbers of those who may have requested a new one.

Confidential information requested

Cohort	All children and teenagers referred to GIDS from or after 1st Jan 2009, resident in England at the point of referral, under 18 at the point of referral, and over 18 at the point the data is shared with NHS England. Approximately 9000 people
Data sources	1. Tavistock and Portman NHS Foundation Trust 2. NHS England a. Hospital Episodes Data – A&E (pre 2019) and Emergency Care Data Set (from 2019) b. Hospital Episodes Data – Outpatient c. Hospital Episodes Data – Admitted Patient Care d. Mental Health Services Minimum Data Set e. Community prescribing data f. Death registration data from the Office of National Statistics (ONS) g. Gender Dysphoria National Surgical Referral System (NRSS) - data held by NHS Arden and Greater East Midlands Commissioning Support Unit h. Gender Affirming Hair Epilation Referral System - data held by NHS Arden and Greater East Midlands Commissioning Support Unit i. GIDS Discharge Audit - data held by NHS Arden and Greater East Midlands Commissioning Support Unit relating to an audit they conducted using GIDS data in 2023 3. Cumbria, Northumberland Tyne and Wear NHS Foundation Trust 4. Sheffield Partnership University NHS Foundation Trust 5. Leeds and York Partnership NHS Foundation Trust 6. Nottinghamshire Healthcare NHS Foundation Trust 7. Northamptonshire Healthcare NHS Foundation Trust 8. Mersey Care NHS Foundation Trust 9. GTD Healthcare Ltd (Indigo)

	10. Tavistock and Portman NHS Foundation Trust 11. Chelsea and Westminster Hospital NHS Foundation Trust 12. Devon Partnership NHS Trust
Identifiers required for linkage purposes	1. Date of birth 2. NHS number 3. Postcode 4. Birth sex
Identifiers required for analysis purposes	1. Month/year of birth 2. Age 3. Birth sex 4. Ethnicity 5. LSOA (deprivation score)

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 has been provided.
2.	Security assurances for 2024/25 are outstanding for the following organisations. o GTD Healthcare Ltd (Indigo) 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.	Due to the number of participating organisations involved, It is the responsibility of NHS England, as controller, to ensure that 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 about an organisation.
3.	Confirm whether the inclusion criteria will be over the age of 18 at the point of data collection, or	The applicants confirmed that organisations will be asked to share information relating to individuals

	at the point of data analysis, with justification. Please provide an updated protocol with new version number and date, if the decision alters from that currently stated.	who are already aged 18 or over at the point the data is shared with NHS England, with relevant documents updated. CAG accepted this response
4.	The CAG request that further public involvement is conducted with a proportionate, representative and diverse group. Topics that should be discussed include: a. Test the acceptability of using confidential patient information without consent b. Discuss the views of the study being undertaken by NHS England c. Ensure the safeguards of patient information that will be in place are highlighted. d. Present the revised notification materials to obtain feedback on the accessibility and readability of information provided.	The applicants planned and undertook further public involvement, incorporating the requests 4a-d from CAG. CAG noted the effort to seek these views and accepted the work done to date, reiterating that it is essential for public involvement to continue for the duration of the research.
5.	The CAG request that the following changes are made to the patient notification materials a. Ensure that all information is written using clear language b. Present the information using a layered approach, structured by section by including clear information on the notification process,	The applicants provided updated notification materials that incorporated requests 5a-e. CAG accepted the response.

	clarification on FAQs and detailed explanation on the opt out process c. State that individuals are able to opt out of the study up to six weeks prior to the commencement of the data collection process d. Provide details on how to access the study specific opt out e. State that some people may have had a national data opt out enacted on by their parent or guardian whilst they were a child and therefore do not need to utilise the national data opt out. Explain that those who wish to opt back in the study can do so	
6.	Include milestones to the communications plans to provide clarification of when study activities will take place. It is not expected that specific calendar dates are provided but it is advised that timescales are provided	The applicants updated the communication plan with relevant timings CAG accepted the response.
7.	Ensure that patient notification materials are circulated up to 6 weeks data collection take place rather than 4 weeks. This is so people are able to opt out prior to data being shared.	NHS England noted and agreed to the request, with relevant materials updated. CAG accepted the response.

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**
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: Due to the number of participating organisations involved, It is the responsibility of NHS England, as controller, to ensure that 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 about an organisation.

1.2	**26/CAG/0079**	**Evaluation of the clinical impact and cost-utility of a comprehensive digital diabetes self-management platform (MyWay Diabetes): a mixed-methods, pragmatic, real-world evaluation**
	Chief Investigator:	Professor Martin Rutter
	Sponsor:	The University of Manchester
	Application type:	Research

Present:

Name	Capacity
Mr Dan Roulstone	CAG Vice Chair
Dr Malcolm Booth	CAG Member (Expert)
Dr Sandra Duggan	CAG Member (Lay)
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 The University of Manchester is for the purpose of medical research to assess whether MyWay Diabetes (MWD), is suitable for commissioning across England, by reviewing its clinical effectiveness, cost-effectiveness, equity, usability and acceptability across diverse groups, and how it can be improved.

MWD developed by MyWay Digital Health Ltd (MWDH), has potential to transform diabetes self-management across NHS England, providing very low-cost support for people with diabetes. The rapidly accelerating burden of diabetes is a global health emergency. Diabetes and its complications consume 10% of NHS spending, where 80% of this is spent treating largely preventable complications. However, diabetes monitoring and treatment targets are seldom achieved and there are important disparities in quality of care disproportionately affecting ethnic minority and socioeconomically disadvantaged groups, leading to poorer outcomes. Lifestyle changes necessary to effectively control diabetes mean that self-management and educational support are essential. MWD addresses this issue as it offers an innovative and comprehensive online diabetes self-management website and app with full NHS data integration, aiming to improve health and reduce healthcare burden through empowering people with diabetes to better understand and manage their condition.

's251' support is requested to allow MWDH to disclose identifiers of MWD users to the Secure Data Environment (SDE)s in Greater Manchester and London. This data will be linked to Primary Care data, Hospital Episodes Statistics (HES) data, Secondary Uses Service (SUS) data, and Civil registrations - Deaths data by the SDE teams. The SDE teams will also provide a matched control cohort, of people with diabetes who are non MWD users, however 's251' support for that element is covered by the broad 's251' support the SDEs have already.

For the Somerset region, MWDH will access primary care data from all GP practices in Somerset. However, it will not be possible to link primary care data with HES, SUS, or Civil registrations - Deaths data. MWDH will be processing data that it already handles as part of its contractual service delivery within Somerset. However, with regards to linking the MWD user data to the primary care data, and additionally identifying a matched control cohort, (which are outside of the scope of the direct care purposes MWDH have access to GP records for) 's251' support is requested to provide the common law legal basis for MWDH to access somerset GP data of both MWD users and non users.

SDE teams and MWDH staff (regarding Somerset patients) will then pseudonymise the data. This will then be available in effectively anonymous format, for The University of Manchester study research team to access remotely via the 2 SDEs (for Manchester and London) and a secure environment within MWDH (for Somerset).

Applicants are also seeking consent for MWD users to complete useability & usefulness questionnaires, however this is outside the scope of 's251' support, as users have already consented to be approached via email including invitations to complete usability questionnaires.

Confidential information requested

Cohort	Approximately 66,000 MWD users (excluding only people with gestational diabetes), registered with MWD prior to 1st April 2026 with a GP in Somerset (n=12,207), Greater Manchester (n=23,532) or NW

	London (n=30,542). Control group (only for Somerset): people with diabetes who are non-MWD users - For each user, 5-20 controls not registered with MWD will be identified, matched for age (±2 years),sex, ethnicity, diabetes type, general practice (exact matching). The study will start with a large, matched sample, which will be refined with additional criteria to better balance the groups, using more covariates, if sufficient controls remain available (so 61,035-244,140 Somerset controls total) Data will be extracted from the SDEs in Greater Manchester and Northwest London, and from the temporary SDE in Somerset on or after 1st October 2026 and will extend retrospectively to 36 months prior to the date of MWD user registration (index date). The follow-up period will span from MWD registration up to the data extraction date on or after 1st October 2026. Registration dates up to 1st April 2026 will be used to allow at least 6 months of follow-up. This date will be moved forward appropriately in the event that data is extracted after 1st October 2026. For matched controls, data will be extracted over the same period; 36 months prior to the intervention index date of their matched participant and up to data extraction date on or after the 1st October 2026
Data Sources	• Myway Digital Health Limited- Database of MyWay Diabetes (MWD) users • Greater Manchester (North West) Secure Data Environment (SDE) – CAG ref: 24/CAG/0034 o MWD users and non-users and link to primary care, SUS, HES and ONS data 2016-26 • One London Secure Data Environment (SDE) CAG ref: 24/CAG/0155 o MWD users and non-users and link to primary care, SUS, HES and ONS data 2016-26 • 60 Somerset GP practices medical records, accessed by Myway Digital Health Limited via their usual route.
Identifiers required for linkage purposes	**GM and London SDE** for cases:

	• NHS numbers for MWD users in each region • (controls created using the broad 's251' support afforded to SDEs, in order to provide an effectively anonymous dataset for analysis, and so is outside the scope of this 's251' support) **Somerset** for cases and controls: • NHS number for MWD users • NHS number for matched controls, extracted using access to GP record
Identifiers required for analysis purposes	N/A – no identifiers required for analysis

Confidentiality Group Advice

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

	Action required	**Response from the applicant**
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	REC confirmed the applied conditions were met on 8 September.
2.	Provide full details of the study-specific opt-out process, including how opt-out requests will be received, verified, managed and applied to ensure that individuals' data are excluded from the study.	Opt-out requests will be received through a secure online form and verified by authorised MWDH staff. Verified requests will be recorded in a secure log and applied before any disclosure, linkage or creation of study datasets for registered MyWay Diabetes users across all three regions and for potential controls in Somerset. Where a subsequent opt-out request is received while data remain identifiable or linkable, the individual's data will be removed and the relevant datasets reconciled accordingly. Completion of the opt-out process will be documented to provide a clear audit trail. The CAG were content with this explanation, and request that there

		should be a period of 4-6 weeks for people to opt-out before the research starts.
3.	The CAG request for the following changes to be made to the patient notification materials: a) Submit copies of the patient notification materials for the controlled cohort for review. b) Include information about the study-specific opt-out process and how individuals can access these rights (contact methods).	These changes were made to the materials and CAG were content with the changes. The applicant also stated that the materials will be reviewed by the study PPIE group to ensure that the information about the study and the opt-out process is clear and accessible. Any feedback received through PPIE and resulting changes to the materials will be documented and communicated with CAG.
4.	Provide further information regarding public involvement activities, including: a) How ongoing public involvement will be conducted throughout the study. b) How the public involvement group will be maintained as diverse, proportionate and representative of the study population.	a) The applicant explained that the study-specific public involvement group has been involved throughout the study to date, meeting seven times at approximately 3–4 monthly intervals. Members have made substantial contributions to the project, helping to shape and provide feedback on key elements of the study. For the remainder of the project, three further group meetings are planned through to winter 2028. Meetings will be less frequent as the study progresses, reflecting the remaining activities and the group's needs. Members will also be able to contribute between meetings where specific questions or tasks arise. applicants anticipate involving the group in the interpretation of emerging findings and the development and dissemination of study outputs. Where further input is needed, applicants can either bring the group together for a focused discussion or seek their views remotely, depending on the nature and timescale of the work. This will ensure that public involvement

		remains available throughout the remaining study period rather than being limited to the planned meetings. b) The public involvement group consists of six people living with type 2 diabetes drawn from across the three study regions. The group includes current MyWay users, people who have previously used MyWay Diabetes and people who have not used the platform, ensuring that the group incorporates perspectives from people with differing experience of MyWay Diabetes and digital diabetes support. When establishing the group, applicants sought to include a range of characteristics and experiences relevant to the study population and to engagement with digital health. The group has an equal gender balance (50:50) and includes people from a range of ethnic backgrounds, with four of the six members from African Caribbean and South Asian backgrounds, reflecting important demographic groups within diabetes support and specifically the populations served by the study sites. The group also brings a range of circumstances and experiences that may influence access to and engagement with digital health, including having English as a second language, being largely housebound, and having differing levels of confidence and experience with digital technology. The composition of the group will be kept under review as the study progresses. Applicants will consider whether the perspectives represented remain appropriate to

		the issues being addressed and whether important perspectives are missing. Where gaps are identified, or where a particular aspect of the study would benefit from additional perspectives, applicants will seek targeted input from additional people with relevant lived experience alongside the existing group. Given the size and purpose of a public involvement group, it is not intended to be statistically representative of the wider study population. Rather, the approach is to maintain a group that is diverse and proportionate to the study's needs and that reflects a range of characteristics, experiences and perspectives particularly relevant to people with diabetes and to the use of digital diabetes support. CAG noted these responses and accepted that this was sufficient to provide 's251' support. CAG included a condition to expand the public involvement activities to include more people over the next year, and report back to CAG on ongoing public involvement activities at first annual review.
5.	Submit a copy of the communications plan detailing how the study population (including the control group) will be informed about the study.	A plan was submitted. Registered MyWay Diabetes users will be informed through the study webpage and through the invitation to complete the usability questionnaire and accompanying PIS from MWDH. Somerset users may also become aware of the study through GP-practice posters and communications distributed through relevant healthcare, community or charity channels. In Somerset, where the study-specific opt-out also applies to people with diabetes who may be included in the control group, awareness will be supported through GP-practice poster/flyer, with introductory email, and

		onward GP communications through relevant clinical and healthcare channels. These materials will direct individuals to the study webpage, which provides further information about the study, how health information will be used, and how eligible individuals can exercise the study-specific opt-out. To maximise awareness across the study population, these approaches will be supplemented by communications through MWDH, the University of Manchester, Somerset ICB and relevant community or social-media channels. Together, these complementary routes are intended to provide proportionate and accessible notification of the study, including for individuals who may be included in the control population. CAG were content with this explanation.
6.	Confirm the study population and provide clarification on the eligibility criteria, including whether individuals living with type 1 diabetes, type 2 diabetes, or both will be recruited.	The retrospective matched-cohort study will include adults aged 18 years or over with a diagnosis of type 1 or type 2 diabetes; people with gestational diabetes will be excluded. The user cohort comprises approximately 66,000 people registered with MyWay Diabetes for at least six months and with a GP in Somerset, Greater Manchester or Northwest London. Each user will be matched with 5–20 non-users with diabetes from the same region, initially on age, sex, ethnicity, diabetes type and general practice. The same diabetes eligibility criteria will apply to users and matched non-users. The study-specific Section 251 request covers the Somerset user and control cohorts; the Greater Manchester and Northwest London control cohorts are created within the relevant Secure Data Environments (SDEs) under their existing Section 251 support.

		The optional usability questionnaire will also be offered to adult registered MyWay Diabetes users with type 1 or type 2 diabetes. CAG were content with this response.
7.	Provide clarification on the proposed data retention period and associated study exit strategy.	In relation to the study-specific opt-out procedure, identifiable information submitted through the form will be retained only for as long as necessary to verify and apply the request, reconcile all relevant study datasets and address any associated query or complaint. It will then be securely deleted in accordance with the approved retention schedule. CAG noted this, however any identifiers retained with regards to opt out are with the consent of the participant to process identifiers with regards to opting out, rather than with 's251' support. In relation to the research study in general, data will be retained only for as long as necessary to complete the study analyses and reporting. Specifically, the data will be retained until both (a) the study findings have been published in a peer-reviewed journal and (b) the final NIHR study report has been completed. Applicants anticipate that both outputs will be completed by 31 December 2028. Once these activities are complete and the data are no longer required for the approved study purposes, access to the study datasets will cease and the data will be securely deleted or otherwise disposed of in accordance with the requirements of the relevant data providers and SDEs. No study data will be retained beyond this point unless required by the applicable data governance arrangements. CAG accepted this response.

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 expand the public involvement activities to include more people over the next year, and report back to CAG on ongoing public involvement activities at first annual review
2.	The CAG request that there should be a period of 4-6 weeks for people to opt-out before the research starts.
3.	Favourable opinion from a Research Ethics Committee. **Confirmed (FIFO 08 September 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:** Due to the number of participating organisations involved, it is the responsibility of The University of Manchester as controllers, to ensure that 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 about an organisation

1.3	**26/CAG/0090**	**IMAGINE PACT: Imaging Dataset Curation for the Multicentre Validation of PACT-UK (Pancreatic Cancer Reporting Template UK)**
	Chief Investigator:	Dr Ganesh Radhakrishna
	Sponsor:	The Christie Hospital NHS Foundation Trust
	Application type:	Research

Present:

Name	Capacity
Prof. Will Bernal	CAG Alternate Vice Chair
Dr Malcolm Booth	CAG Expert Member
Ms Cath Trigwell	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 The Christie Hospital NHS Foundation Trust is for the purpose of medical research to assess the inter-rater and intra-rater reliability of the PACT-UK structured reporting tool for pancreatic cancer CT imaging across multiple NHS sites, establishing whether standardised structured reporting achieves acceptable and reproducible consistency for multicentre research and clinical application.

Pancreatic cancer is one of the most serious cancers in the UK, with fewer than one in ten patients surviving five years after diagnosis. When pancreatic cancer is suspected, CT scans are used to assess the tumour and determine the best course of treatment, in particular, whether surgery is possible. However, the content and style of radiology reports can vary between radiologists and between hospitals, making it difficult to compare scans, plan treatment consistently, and use imaging data for research.

To address this, a structured reporting tool called PACT-UK was developed. Rather than writing a free-text report, radiologists complete a standardised checklist. Structured reporting of this kind has the potential to improve clinical decision-making, support multidisciplinary team discussions, and enable research across multiple hospitals. PACT-UK is already in clinical use across NHS specialist centres, but existing published work describes only how the tool was developed, not how consistently radiologists use it in practice. Early testing found full agreement between radiologists in fewer than one-third of cases when assessing vascular involvement, one of the most clinically important elements of the report. This suggests that without formal validation, the same scan could be reported differently depending on which radiologist completes it, with potential consequences for treatment decisions.

IMAGINE PACT is the first study to formally and systematically assess how consistently PACT-UK is used across multiple NHS hospitals, using a statistically robust methodology. Radiologists will independently report the same set of scans, and results will be compared to assess reliability in real-world NHS practice. Where inconsistencies are identified, the tool will be refined. The findings will directly inform whether PACT-UK is ready for widespread national adoption as a clinical and research standard.

Prospective patients will be consented, however 's251' support is sought for the participating sites to extract effectively anonymous data and imaging for retrospective patients, to disclose this to The Christie Hospital NHS Foundation Trust (data) and The Institute of Cancer Research (imaging).

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

Confidential information requested

Cohort	Adults 18 or over with suspected or confirmed non metastatic pancreatitic neoplasm undergoing CT/MRI imaging. The retrospective cohort comprises eligible cases identified within the preceding 24 months from study commencement at each site where it is not reasonably practicable to obtain informed consent. It is only the retrospective cohort that are relevant for 's251' support. ~3,000 imaging datasets (scan + PACT-UK report) – However the applicant anticipates approximately 20% (around 600 datasets) will be retrospective and therefore included with 's251' support.
Data sources	Pancreatic CT scans, together with their associated PACT-UK structured reports. MRI scans acquired as part of routine NHS care may be collected where available, from 5 Participating English sites: • Manchester University NHS Foundation Trust • The Royal Marsden NHS Foundation Trust • Leeds Teaching Hospitals NHS Trust • The Newcastle upon Tyne Hospitals NHS Foundation Trust • Cambridge University Hospitals NHS Foundation Trust
Identifiers required for purposes of cohort identification, data extraction and pseudonymisation	Clinical records including: • name • NHS number • Hospital ID • date of birth • unit level postcode
Identifiers required for analysis purposes	N/A – effectively anonymous for analysis (as central team do not have means to re-identify)

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 note that some public involvement has been conducted. Further information and action is requested as below: a. Provide more information on the content of the questionnaires, including on the specific use of confidential patient information in the retrospective cohort from the 8 contributors. b. Provide more information on the outcomes from the one-hour virtual meeting from 2 contributors, and include if they were supportive of the project. c. Further public involvement should be conducted to address the use of retrospective data. This should be either face-to-face or via videoconference.	The applicants provided the questionnaire content, as well as further information from the one-hour virtual session. A commitment was given to undertake further public involvement. CAG were generally content with this but requested an update on the public involvement within six months [Condition 1].
2.	The CAG request the following actions in relation to the fair processing notification materials: a. Add in the names of the participating centres b. include contact information for each centre for opt out	The fair processing materials were updated in line with points 2a-d,and CAG were content with these.

	purposes c. 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)'. d. Include an opt out route via the sponsor.	
3.	a. Submit the website text. b. Add a short statement on the Pancreatic Cancer UK's webpage with a link to the full IMAGINE PACT information and study-specific opt-out page.	The website text was provided, including the short statement requested in point 2b. CAG were content with the text.
4.	The CAG acknowledge the importance of retaining the pseudonymisation key for 5 years after the end of the study, but request justification as to why the research team should hold the key rather than the direct care team.	The applicant's confirmed that the key will be retained within the research team at the local site, noting this will keep it within the control of string research governance processes. The central research team will not have access to this. CAG accepted the response

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.	Undertake further public involvement related to the use of confidential patient information without consent for the retrospective cohort, following

	CAG guidance. An update should be provided within 6 months.
2.	Favourable opinion from a Research Ethics Committee. **Confirmed**
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:** Due to the number of participating organisations involved (NHS Trusts), it is the responsibility of The Christie Hospital NHS Foundation Trust as controllers, to ensure that 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 about an organisation.

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/0075**	**Pre-hospital care for older adults: a mixed methods evaluation**
	Chief Investigator:	Professor Simon Conroy
	Sponsor:	Queen Mary, University of London
	Application type:	Research

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair
Cath Trigwell	CAG Lay Member
Martin Andrew	CAG Expert Member

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 conditions in correspondence.

The following conditions have been confirmed as being met:

Number	Condition
1.	Please provide the comments/feedback from the public involvement meeting planned for 19 August, when this is available.

2.2	**25/CAG/0136**	**Impact of Body Composition in Curative Radiotherapy**
	Chief Investigator:	Alexander Vickers
	Sponsor:	University of Manchester
	Application type:	Research

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 conditions in correspondence.

The following conditions have been confirmed as being met:

Number	Condition
1.	Members asked that the following revisions are made to the Participant Information Sheet: a. The information about the project specific opt-out needs to be placed before the information about the National Data Opt-Out. b. A PPI review should be undertaken to ensure that the information makes sense to the reader before it is rolled out. Conditions confirmed as met **16 September 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 **24/25** DSPT review for **The Christie NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker.

3.	Favourable opinion from a Research Ethics Committee. **Confirmed 28 October 2025.**

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	**23/CAG/0122**	**NHS Derby and Derbyshire Integrated Care Board - Disclosure of combined commissioning data sets and GP data for risk stratification purposes to Integrated Care Boards and Data Processors**
	Contact:	Ged Connolly-Thompson
	Data controller:	NHS Derby and Derbyshire Integrated Care Board
	Application type:	Non-research

Present:

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair

Also in attendance:

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

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

Summary of modification request

This application has ‘s251 ‘support for risk stratification NHS Derby and Derbyshire Integrated Care Boards (ICB) on their population. Risk stratification is a tool to identify patients that are at high risk of health deterioration and may require use of multiple services. This identification allows GPs to prioritise the management of their care to reduce and prevent poor outcomes. Risk stratification necessitates the use of large scale, whole ICB population, use of national datasets combined with GP data. Support is in place for the flow of confidential patient information from GP suppliers to the risk stratification supplier and to link this information with national datasets through NHS number.

An amendment, seeking to include a new purpose of processing to this application, of wider population health management (PHM), where there is no direct impact on individual care, and where the purpose of the processing is to commission, design or manage services for the benefit of the wider population and the NHS, was supported in November 2025.

In this request, the applicants seek to make the following changes:

Change the supported purpose/operating model to align the existing s251 arrangements so the three legally separate ICBs can undertake risk stratification and population health management collaboratively.

Extend the Nottingham and Nottinghamshire model, using the GPRCC and eHealthScope model consistently across the wider cluster for linkage, pseudonymisation and analysis.
Changes to organisational roles to reflect the involvement of the three ICBs and Nottingham Health Informatics Service, hosted by Sherwood Forest Hospitals NHS Foundation Trust, in the controller/processor arrangements.

An interim clustered arrangement. This will remain in place until longer-term shared infrastructure, governance arrangements or a merged ICB model supersedes it. The applicants explained that the clustering of the Derby & Derbyshire, Nottingham & Nottinghamshire and Lincolnshire ICBs, is driven by national NHS policy to reduce running costs and improve efficiency, combined with a strategic objective to strengthen commissioning capability, enable population health management at scale, and support delivery of the NHS 10-Year Plan through greater system integration and sustainability.

It is expected that the three ICBs in the DLN Cluster will formally merge into a single ICB. Until this happens, they will continue to operate as three separate legal entities with a shared board, shared Executive Team, Senior Leadership Team and employees working together in a matrix management function to effectively operate as a single entity.

The impact upon data flows to be able to deliver at this level will require the sharing of information across employees from all three organisations. Currently, all three ICBs have different information systems supporting their risk stratification and population health management functions. The applicants provided a revised data flow diagram, reflecting the clustering arrangements.

Confidentiality Advisory Group advice: *Conditionally supported*

The CAG Officer 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 notification materials are currently in the process of being reviewed and updated. Please provide the materials, once updated, for review by the Confidentiality Advice Team.
2.	Please consider expanding public involvement to include local people, so that the views of the cluster population are represented. This should be reported back on at annual reviews.
3.	Further changes to the patient notification materials may be needed at the point when there is a unified ICB. A further medication may need to be submitted to provide these documents for review.
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: 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.

3.2	**23/CAG/0046**	**Thames Valley and Surrey Secure Data Environment**
	Chief Investigator:	Ben Attwood
	Sponsor:	Oxford University Hospitals NHS Foundation Trust
	Application type:	Research Database

Present:

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

Also in attendance:

Name	Position (or reason for attending)

Dr. Paul Mills	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 Thames Valley and Surrey (TVS) Secure Data Environment (SDE) currently has Section 251 support for all NHS primary and secondary care organisations who provide NHS treatment within the Thames Valley and Surrey area to share confidential patient information with Oxford University Hospitals 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 TVS SDE to process confidential patient information to enable sharing of pseudonymised information with other SDEs for multi-SDE projects. It also enables TVS SDE to act as the 'Prime' (lead) SDE, whereby other SDEs will share pseudonymised information to TVS 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 used 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 TVS 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.

Relating to patient notification materials, embers requested a number of updates to the leaflets, poster and website to make it clearer to the public how their identifiable information is used within the SDE, and how information may sometimes be shared with other SDEs. These were all satisfactorily responded by the applicants and CAG were content. Members noted that the response to CAG contained proposed updates, requested the updated versions of the poster and leaflet when these changes have been made **[Condition 1]**.

Regarding the website, CAG considered it was difficult to navigate to the important information from the perspective of a member of the public. As such, CAG agreed that support was conditional on the SDE reviewing and updating the information for the public on the SDE website. As part of this, the role of SARC and the involvement of patients and the public should be clearer on the Governance page. Currently, the

role of patients is within the terms of reference only, which was not felt overly transparent. Doing so may provide more transparency and trust to how decisions are made. An update on progress should be provided at next annual review. **[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 at next annual review. **[Condition 3].**

Members noted the modification did not include provision to share confidential patient information with other SDEs, which will be requested on a project specific basis.

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.	Provide updated versions of the poster and leaflet, once available.
2.	At next annual review, provide an update on ensuring the SDE website is easier to navigate from a patient perspective, including ensuring that the public role on SARC is more transparent.
3.	At next annual review, provide an update on further public involvement the SDE has undertaken, including n multi-SDE projects.
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:** Due to the number of other participating organisations involved it is the responsibility of Oxford University Hospitals 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.
5.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed**

3.3	**18/CAG/0180**	**LAUNCHES QI: Linking AUdit and National datasets in Congenital HEart Services for Quality Improvement**
	Chief Investigator:	Dr Christina Pagel
	Sponsor:	University College London
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)
Ms 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 has existing support to link to a number of national datasets for the purpose of medical research which aims to improve services for congenital heart disease and provide a template for other lifelong conditions.

This modification sought support to extend the duration of 's251' support, for retention of confidential patient information, until 31 December 2027.

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:** Due to the number of organisations involved it is the responsibility of University College London, as controller, to ensure that 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 about an organisation.
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed notification only on 21 September 2026.**

3.4	**24/CAG/0067**	**PregnAncy Risk assessmenT aNd dEcision suppoRt (PARTNER): A Clinical Decision Tool To Reduce Placental Disorders and Preterm birth in Pregnancy**
	Chief Investigator:	Dr Christy Burden
	Sponsor:	University of Bristol
	Application type:	Research

Present:

Name	Capacity
Professor Lorna Fraser	CAG Chair

Also in attendance:

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

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

Summary of modification request

The applicants have existing support to allow the disclosure of confidential patient information from participating NHS trusts to the University of Bristol, NHS England and King's College London.

In this request, the applicants seek to refocus the study as a feasibility study. Only Work Package 1 will be undertaken, and Work Packages 2 and 3 will be discontinued.

These changes mean that nine participating NHS trusts will be removed. King's College London and the University of Sheffield will also no longer be data processors, following discontinuation of Work Packages 2 and 3.

The applicants also plan to offer sites originally allocated to the standard care arm the opportunity to cross over to the intervention arm.

Support is sought to allow limited, delegated access by nominated study team members to participant-level data within the CDS Tool. This will be undertaken solely for troubleshooting purposes, where data quality or linkage issues cannot be resolved by other means. Access will be logged, restricted to named individuals on the delegation log, and conducted in accordance with the existing s251 support and the trial data management plan.

Revised versions of affected documents, including the protocol and statistical analysis plan, are submitted alongside this letter. The revisions are to reflect the

changed study design, processor arrangements, discontinued data transfers and restricted troubleshooting access.

No change to the data items, data sources, data controller or duration of support are requested.

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 review for **NHS England, University of Bristol & University Hospitals Bristol and Weston NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 24 September 2026).
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 19 August 2026.**

3.4	**26/CAG/0051**	**Surveillance of invasive Group B streptococcal (iGBS) disease in infants up to 90 days of age in the UK and Ireland**
	Chief Investigator:	Dr Konstantinos Karampatsas
	Sponsor:	City St George's, University of London
	Application type:	Research

In attendance:

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

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

Summary of modification request

This application from City St Georges University of London was supported for the purpose of medical research to estimate the incidence of invasive Group B streptococcal (GBS) disease in infants under 3 months old, in the UK and Republic of Ireland, to establish incidence, and characteristics of these children. Data will be collected over a 13-month surveillance programme operating via the British Paediatric Surveillance Unit (BPSU) methodology, using the monthly reporting card amongst UK paediatricians.

Following discussions with Welsh Health Boards, Welsh clinicians have expressed a reference for Welsh data to be shared to Public Health Wales. Here, it will be linked to microbiological data from UKHSA. At the end of the study, Public Health Wales will create an anonymised database to share with the research team.

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 25/26 DSPT review for UK Health Security Agency (UKHSA) was confirmed as 'Standards Met' on the NHS England DSPT Tracker Due to the number of participating reporting paediatricians involved it is the responsibility of City St Georges University of London as controller, to ensure that these participating organisations meet the minimum required standard in complying with DSPTs, or Welsh Information Governance Toolkits (WIGTKs) and take remedial action if they become aware of any that fall below this, or where any concerns are raised
2.	Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed

4. Annual reviews supported

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

CAG reference	Title	Comments
22/CAG/0064	BE SURE	

24/CAG/0108	Overarching Research Database Approval for the NCAPOP	
16/CAG/0058	National Maternity and Perinatal audit	

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
23/CAG/0072	Listen2Baby - Improving monitoring of the baby during uncomplicated labour: a study using experience-based co-design
24/CAG/0089	HUB-API - Clinical Deterioration Prediction Modelling
24/CAG/0052	The Development of a Combined Multi-Modal NonInvasive Biomarker Screening Approach for High-Risk Undiagnosed Liver Disease
24/CAG/0159	Improving maternity and neonatal care in England: a formative evaluation of the implementation of the Core Competency Framework to improve multi-professional practice.
25/CAG/0083	SASI-MEDS

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*