Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

March 2024

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1. NEW APPLICATIONS (RESPONSE TO PROVISIONAL OR CONDITIONAL OUTCOME)

1.1	**23/CAG/0147**	**Cheshire and Merseyside: System Supplier processing of Confidential Patient Information to create a de-identified data mart for secondary uses**
	Contact:	Rowan Pritchard-Jones
	Data Controller:	Cheshire and Merseyside Integrated Care Board (ICB)
	Application type:	Non-research

Present:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Dr Martin Andrew	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Ms Rose Payne	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 considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from Cheshire and Merseyside Integrated Care Board (C&M ICB) sets out the medical purpose to create a resource for secondary non-research use of the patient information in the C&M ICB footprint. This will be closely linked to the North West Secure Data Environment (SDE) following a future research application, but this is separate from the wider NHS England sub-national SDE programme, and is specific to Cheshire and Merseyside.

The data will be used for a wider range of secondary non-research uses, including population health management and commissioning intelligence. Use of data will be through a model of data access, rather than data sharing. Use cases will be considered by the Data Asset and Data Access Group (DAAG), which has two public members and will ensure that any uses have a medical purpose and public interest.

Information from national datasets, data from the C&M Care Record, and local datasets (for example local authority data) will be linked using a pseudonymised NHS number. Support is requested for the deidentification and secondary use of data from the C&M Care Record by Graphnet before subsequent linkage.

Confidential information requested

Cohort	All patients who have a health record at an organisation within the Cheshire and Merseyside ICB area.
Data sources	1. GP data from the Greater Manchester Care Record (via Graphnet) 2. Pseudonymised national datasets from Arden and GEM CSU (outside scope of support) 3. Local dataflows deidentified at source (outside scope of support)
Identifiers required for linkage purposes	1. NHS Number

Identifiers required for analysis purposes	None – all data is pseudonymised and then has a further code applied to it to prevent reidentification by the analyst

Confidentiality Group Advice

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

Number	Action required	Response from the applicant
1.	Provide clear justification on why genomic data set is going to be used for the purpose of this application.	The applicant confirmed that genomic data will not be included within the application. CAG were content with this response.
2.	Provide a strategy plan to explain how the applicant is going to target the communication campaign in the future around the people who are not locally residents of Cheshire and Merseyside area.	The applicant clarified that materials will be available at the point of care. This means that anyone accessing services who are not local will still be able to access information. The materials are also being translated into Welsh format. Members were satisfied with the response.
3.	Further patient and public involvement need to be carried out. The discussion should include: a) The specific issue of use of confidential patient information without consent is to be undertaken and feedback provided to the CAG for review. b) Questions around commercial use if the application is planning to use the information for the commercial purposes. c) Provide an ongoing patient and public involvement plan and continuous GP engagement.	The applicant provided a report on further public involvement undertaken. This work covered both the non-research and research uses. A plan was also provided about the further planned public involvement work in the coming months. Members reviewed the information provided and commended the applicants for the detail of the work, both in terms of background and public responses. CAG were content that the condition had been met, and asked for an update at first

		annual review on the continuing public involvement planned.
4.	Please update the patient notification materials as follows, in line with advice in this letter: a) Clearly explain and demonstrate the benefits of the outcome of this application so the patients can understand why their data is going to be used. b) An explanation on how patients can request removal of their data using a local opt-out or the National Data Opt-Out needs to be provided. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data. c) Promote use of the local opt-out whilst still respecting the National Data Opt-Out. d) Patient notification materials should be reviewed by a patient and public involvement group.	The applicants provided update patient materials encompassing these points, plus also including wider comments on the materials. Members were satisfied that all points had been addressed.

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 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.	Ensure that the data access process includes consideration of the medical purpose.
2.	Provide a summary of the outputs of further public involvement work at

	first annual review, as well as a summary whether any changing attitudes that result in a change of approach.
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 22/23 DSPT** review for **Graphnet and Arden and GEM CSU** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (04 March 2024)

1.2	**23/CAG/0151**	**CORECT-R: the UK COloRECTal Cancer data Repository**
	Chief Investigator:	Professor Eva Morris
	Sponsor:	University of Oxford
	Application type:	Research

Present:

Name	Capacity
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Martin Andrew	CAG Member
Mr. David Evans	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Dan Roulstone	CAG Member

Also in attendance:

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

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from the University of Oxford set out the purpose of setting up a research database containing data for all individuals who are at risk of, or are

diagnosed with, colorectal cancer in the UK.

Colorectal cancer is a major public health problem. In the year UK, around 41,000 each year are diagnosed with the disease and 16,000 die from it. High-quality data could be used to improve the outcomes of patients diagnosed with colorectal cancer. Linked colorectal cancer data are already available from some data providers in England, Scotland, Wales and Northern Ireland. However, a UK wide cancer data resource does not exist resulting in researchers and analysts being forced to go through lengthy, resource intensive and costly processes to access numerous cuts of data. The applicants anticipate that CORECT-R will reduce this duplication of effort and increase the security of the data. The first iteration of CORECT-R sought to undertake linkage of datasets within the National Disease Registration Service (NDRS). However, the remit of the NDRS is data generated within England only and the applicants seek to include data from all 4 UK nations.

Support is sought to link data from consented cohort & trial datasets and from datasets held by National Cancer Registration and Analysis Service, NHS England, NHS Bowel Cancer Screening Programme, Health Quality Improvement Partnership, Welsh Cancer Intelligence and Surveillance Unit and Public Health Wales. The datasets will be disclosed to the University of Oxford for linkage. A dataset containing confidential patient information will be held within the CORECT-R Trusted Research Environment.

Researchers seeking to access data will apply via the Hub team. Individuals submit a request and are contacted to discuss their request and availability of data. If the project is feasible, they are then supported to complete a study protocol and to discuss their planned work with the Patient-Public Group. Once complete, the study protocol is considered by the Hub Access Committee. If accepted, and after necessary checks, access is provided to a project specific folder in the CORECT-R Trusted Research Environment. Researchers are only given access to tailored, project specific, pseudonymised datasets in line with their approved protocol.

Confidential information requested

Cohort	All patients in England and Wales with a diagnosis of, or suspect diagnosis of, colorectal and/or anal cancer since 01 January 1997.
Data sources	1. National Cancer Registration and Analysis Service a. Cancer Registry Data b. National Radiotherapy Dataset (RTDS) c. Systematic Cancer Therapy Dataset (SACT) d. Patient Reported Outcomes (PROMS) e. Patient Reported Experience Survey

	2. NHS England a. Hospital Episode Statistics (HES) b. Diagnostic Imaging Dataset (DID) c. Cancer Waiting times (CWT) d. NHS Bowel Cancer Screening Programme 3. Health Quality Improvement Partnership (controller) a. National Bowel Cancer Audit (processors - NHS England and Royal College of Surgeons of England) b. National Emergency Laparotomy Audit (processors - Royal College of Anaesthetists and Royal College of Surgeons of England) 4. Welsh Cancer Intelligence and Surveillance Unit a. Cancer Registry Data b. National Radiotherapy Dataset (RTDS) c. Systematic Cancer Therapy Dataset (SACT) d. Patient Reported Outcomes (PROMS) e. Patient Reported Experience Survey 5. Public Health Wales a. Patient Episode Database Wales (PEDW) b. Bowel Screening Wales
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Occupation 4. Ethnicity
Identifiers held in database	1. Initials 2. Full name 3. Address 4. NHS number 5. Hospital ID number 6. GP registration 7. Date of birth 8. Year of birth 9. Date of death 10. Postcode – unit level 11. Gender

	12. Occupation 13. Ethnicity

Confidentiality Group Advice

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

Number	Action required	Response from the applicant
1.	Provide confirmation that support is only requested for research purposes and a new application for non-research purposes will be submitted separately.	The applicants confirmed that support is only sought for research purposes and a new application would be submitted before any non-research purposes are undertaken. Members noted this response and raised no further queries.
2.	Provide confirmation that the scope of support for this data set is up to 31 May 2023 and application is planning to get consent for the data set post 31 May 2023.	The applicants advised that support will be needed after 31 May 2023 and that consent will not be sought. The data sources are nationally gathered, routine datasets and it will not be possible to prospectively seek consent. The applicants noted that they planned to link data from consented research studies, but this would be under patient consent or a separate CAG application. Members noted this response and raised no further queries.
3.	Further patient and public involvement need to be undertaken with representative groups, to discuss the use of confidential patient information, without consent, for the purpose of this application. Feedback from the discussion is to be	The applicants had drafted a consultation plan in partnership with their Public-Patient Group. The plan includes consultations with relevant cancer charities, patient groups, useMYdata, and other key stakeholders. Feedback would be provided to CAG within 12 months.

	provided to the CAG.	The CAG agreed that the further patient and public involvement needed to be undertaken on the specific issue of use of confidential patient information without consent, and feedback provided, before support could be recommended. The applicants provided feedback form the further public involvement undertaken. Members noted this response and raised no further queries.
4.	Update the patient notification materials to include an explanation on how patients can request removal of their data using a local opt-out or the National Data Opt-Out needs to be provided.	The applicants requested that the application be exempted from application of the National Data Opt-Out. The CAG agreed that, whilst sympathetic to the request, the National Data Opt-Out is a policy position in which patients expect their rights to be upheld. CAG does have the ability to exempt application of the National Data Opt-Out but have only done this for a specific, limited rationale, primarily based on patient safety. CAG has not previously granted exemption for any research projects. As such, and given this is a research application, CAG could not support the request and asked that the poster was updated to reflect this. A project specific opt out is also required for those who want to opt out specifically from this research. The applicant provided information to be displayed online. This explained the research and that patients could

		dissent via the National Data Opt-Out or the study specific opt-out. Members noted this response and asked that the website information was revised so the study specific opt out is stated first. A statement also needs to be added to advise that patients do not need to make a study specific opt-out request if they have already registered dissent via the National Data Opt-Out.
5.	Provide further details on criteria the data access group will use to assess the application, including how the medical purpose will be assessed.	The data access group will follow the applicants Standard Operating Procedures. This has been revised to explicitly include assessment of whether the research fits within the REC Research Database approval. Members 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.	The CAG asked that the website information was revised so the study specific opt out is stated first. A statement also needs to be added to advise that patients do not need to make a study specific opt-out request if they have already registered dissent via the National Data Opt-Out. Please provide the revised website information text within one month of the issuing of this letter.
2.	Favourable opinion from a Research Ethics Committee. Confirmed 02 June 2023.
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 **2022/23** DSPT reviews for **NHS England, Royal College of Surgeons of England, Royal College of Anaesthetists** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 05 March 2024). Caldicott Principles in Practice (CPiP) are in place for **Welsh Cancer Intelligence and Surveillance Unit** and **Public Health Wales.**

1.3	**24/CAG/0011 (Research) and 24/CAG/0012 (Non-Research)**	**Pre-hospital Research and Audit Network (PRANA)**
	Chief Investigator:	Dr Philip Hyde
	Sponsor:	University Hospital Southampton NHS Foundation Trust
	Application type:	Research Database and Non-Research

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Sandra Duggan	CAG Member (Lay) (did not attend for item 4e)
Dr Ben Gibbison	CAG Member (Expert)
Mr Umar Sabat	CAG Member (Expert)

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 detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This is an application from University Hospital Southampton NHS Foundation Trust that proposed to create a resource on all patients who receive pre-hospital critical care at the request of NHS ambulance services, for non-research and research uses.

Ambulance services in 2022/23 nationally attended to 8 million patients. A small proportion (estimated 0.5%) of these patients were so severely ill or injured that their lives were immediately threatened (40,000 patients). These patients received high level pre-hospital critical care from a range of specialist NHS and independent sector CQC registered pre-hospital critical care services. Although these patients are proportionally a small subset of the medical and trauma patients cared for by ambulance services, the potential benefits in terms of reducing morbidity and mortality are disproportionately significant. Whilst patient specific data is collected by the ambulance services across their pre-hospital care pathway, data regarding pre-hospital critical care treatment is not currently collated beyond provider organisations nor linked to outcome. Therefore, the potential systematic improvements created through national data collection, analysis, review and publication are currently absent within UK pre-hospital critical care.

The PRANA registry intends to enable data from critically ill and injured patients' whole care pathways (from moment of recognition of illness or injury onwards) to be utilised to improve understanding of pre-hospital disease, improved diagnosis and treatments of pre-hospital disease, reduce risk for patients and clinicians, evaluate the impact of new professional roles on the UK health economy, enable future service planning and improvement, evaluate the effectiveness of health policy, identify targets for disease prevention, inform prevention of injury and illness and enable future research and innovation.

All pre-hospital services (ambulances/air-ambulances) in England and Wales will flow identifiable information to the Wessex SDE held at University Hospital Southampton NHS Foundation Trust on a quarterly basis. This data will be linked with a range of relevant national datasets and national audits to create a resource to be used for research and non-research purposes. All requests for use of data will be considered by a PRANA data access committee, which includes a lay representative, before agreement by the Wessex SDE data access committee.

Confidential information requested

Cohort	Every patient who has received pre-hospital enhanced or critical care at the request of NHS ambulance services, unless they have chosen that their data should not be used. Estimated to be approximately 40,000 per year, and will be a prospective data collection only.
Data sources	1. University Hospital Southampton NHS Foundation Trust 2. East Midlands Ambulance Service 3. East of England Ambulance Service

	4. Isle of Wight Ambulance Service 5. London Ambulance Service 6. North East Ambulance Service 7. South East Ambulance service 8. South West Ambulance service 9. West Midlands Ambulance Service 10. Yorkshire Ambulance service 11. Welsh Ambulance Service 12. London's Air Ambulance 13. Great North Air Ambulance 14. Air Ambulance Kent Surrey Sussex 15. East Anglia Air Ambulance 16. Lincolnshire, Nottinghamshire Air Ambulance 17. Thames Valley Air Ambulance 18. MAGPAS air ambulance 19. Hampshire and Isle of Wight Air Ambulance 20. North West Air Ambulance 21. Essex and Hertfordshire Air Ambulance 22. West Midlands Air Ambulance 23. Devon Air Ambulance 24. Derbyshire, Leicestershire, Rutland Air Ambulance 25. Warwickshire, Northamptonshire Air Ambulance 26. Cornwall Air Ambulance 27. Great Western Air Ambulance 28. Wiltshire Air Ambulance 29. Dorset and Somerset Air Ambulance 30. Yorkshire Air Ambulance 31. Emergency Medical Retrieval and Transport Service Wales 32. Paediatric Intensive Care Audit Network (PICANet) 33. National Major Trauma Registry (previously called Trauma Audit Research Network) 34. Intensive Care National Audit and Research Centre (ICNARC) 35. Department for Transport – STATS-19 36. Hospital Event Statistics 37. Ambulance data set (NHS England) 38. National Organ Donation Registry 39. Out of hospital Cardiac Arrest Outcomes registry (OHCAO) 40. All Coroner services in England and Wales

Identifiers required for linkage purposes	1. NHS number 2. Patient's first name 3. Patient's family name 4. Patient's date of birth 5. Patient's home postcode
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode 5. Gender 6. Occupation 7. Ethnicity

Confidentiality Group Advice

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

Number	Action required	Response from the applicant
1.	Amend the patient leaflet to: a. provide further information, or a link to the PRANA website containing more information, on how identifiable patient information is used without consent to create the final dataset. b. clearly detail whether it is intended for either patients once recovered or family members	The applicant provided revised, and new, leaflets and posters which took account of the requests from CAG. The applicant also provided links to the updated website information. Members were content with the updated provided and agreed that the action had been met.
2.	Conduct further patient and public engagement sessions, specifically around the use of confidential patient information without consent. Outputs from the sessions should be provided	The applicant clarified the activity that had been undertaken alongside the Wessex Secure Data Environment. In addition, the applicant undertook further public involvement specific to this application and provided CAG with

	to CAG that includes a summary of: a. the number and demographics of participants b. how the use of identifiable patient information was described to participants. c. the responses and discussions on the use of confidential patient information without consent.	a report on the work, together with a summary of the demographics. The CAG were happy to see this further work and support from the public, and agreed the action had been met.

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 and the Secretary of State for Health and Social Care, 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: The NHS England ***22/23*** DSPT review for **University Hospital Southampton NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 05 March 2023)

1.4	**24/CAG/0033**	**North West Sub National Secure Data Environment: Cheshire and Merseyside ICB**
	Chief Investigator:	Helen Duckworth
	Sponsor:	Cheshire and Merseyside ICB
	Application type:	Research Database

Also in attendance:

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

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome.

Summary of application

This application from Cheshire and Merseyside Integrated Care Board (C&M ICB) sets out the medical purpose to create a create a research database

Cheshire and Merseyside ICB are developing the Northwest sub-national Secure Data Environment (SNSDE). This is part of a national initiative to move towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy. SNSDEs across the country will also become interoperable to enable access. Further details on this national initiative and progress to date is here. Note that the Northwest SDE is using a federated approach and each ICB in the North West is submitting separate applications (Greater Manchester ICB in this meeting, and Lancashire and Cumbria at a later date).

C&M ICB are linking data from multiple sources to create a deidentified dataset for research use. Support is requested for Graphnet to pseudonymise the local shared care record and share with Arden and GEM CSU (processing on behalf of C&M ICB), for Arden and GEM CSU to pseudonymise national datasets processed by Data Service for Commissioners Regional Office (DSCRO) for use in the SDE, and for local organisations to share identifiable information to Arden and GEM CSU, where they are unable to pseudonymise at source. Other national sources are shared under Directions, or pseudonymised at source and are outside the scope of CAG. Support is also requested for the retention of confidential patient information within the SNSDE environment.

Requests for data access are governed by the Data Access and Asset Group. The group contains a range of members, including two lay members. Whilst this is currently specific for C&M ICB, there are plans to consolidate to have one data access route in the Northwest.

Confidential information requested

Cohort	The registered and resident population of Cheshire and Merseyside and the individuals who have received care at the providers within Cheshire and Merseyside.

Data sources	1. Local Shared Care record (GP data via Graphnet) 2. Data sources processed by Data Service for Commissioners Regional Office (DSCRO) at Arden and GEM CSU a. Alcohol Dependence b. Ambulance Data c. Assuring Transformation (learning disabilities) d. Community Services Dataset e. Clinical Audits and Registries f. Continuing Health Care g. CVD Prevent h. Diagnostics Imaging Dataset i. e-referral system dataset j. Faster Data Flows k. Maternity Services Dataset l. Medicines dispensed in primary care m. National cancer waiting times n. NHS Pathways Dataset (111/999) o. Patient reported outcomes dataset (PROMS) p. Patient Level Contract Monitoring (Pathology tests done) q. Virtual Wards r. Telehealth Service s. Civil Registrations Births t. Civil Registrations Deaths 3. National Data Sources covered under the national NHS Direction from health and social care for use for research a. Secondary Users Service (SUS) b. COVID 19 Data Assets c. Improving Access to Psychological Therapies d. Mental Health Minimum Dataset e. National Diabetes Audit f. Summary Hospital Mortality Indicator set (SHMI) g. Adult Social Care 4. Local organisation data a. Pseudonymised at source b. Unable to be pseudonymised at source
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode

Identifiers required for analysis purposes	1. Year of birth 2. Gender 3. Ethnicity 4. Lower Super Output Area

Confidentiality Advice Team Advice

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome 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.	The Research Ethics Favourable Opinion was issued on 6 March 2024, enabling support to be issued.

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 requests the following regarding patient notification materials: a. Confirm whether a Welsh version of the patient notification materials was possible. b. Provide CAG with the most up to date lay-friendly patient notification materials.
2.	Ensure that the data access process includes consideration of the medical purpose.
3.	Provide a summary of the outputs of further public involvement work at first annual review, as well as a summary whether any changing attitudes that had resulted in a change of approach.
4.	Favourable opinion from a Research Ethics Committee. **Confirmed** 06 March 2024

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 **22/23** DSPT review for **Graphnet** and **Arden and GEM CSU** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (04 March 2024)

1.5	**22/CAG/0111**	**Research database for Biliary Atresia (England & Wales)**
	Chief Investigator:	Professor Mark Davenport
	Sponsor:	Kings College Hospital NHS Foundation Trust
	Application type:	Research Database

Present:

Name	Capacity
Dr Tony Calland MBE	CAG Chair

Also in attendance:

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

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This research application from Kings College Hospital NHS Foundation Trust (KCH) set out the purpose of creating a research database of all infants with biliary atresia in England and Wales from Jan 1999 onwards.

A non-research registry has 's251' support in place (CAG ref: 21/CAG/0150) in order to monitor the outcome of the clinical management of biliary atresia. This registry has been in existence since 1999 when the Department of Health mandated that a record be kept of all infants in England and Wales with this diagnosis. The purpose of the research

database is to allow the applicant to perform research analyses on the data collected, as further analysis on this unique and valuable resource will lead to a better understanding of the aetiology of this disease. An example of a research question is to determine demographic features of cohort of infants born within England and Wales with diagnosis of Biliary Atresia, and the protocol for this epidemiology study has been included. The data from this research database will not be supplied to researchers who are not linked to the non-research registry, as such there is no data access committee. Rather it is to allow the Chief Investigator and other co-investigators at the hospital sites an opportunity to analyse the data for research purposes.

Biliary atresia is a rare, potentially life-threatening, condition of new-borns characterised by persisting jaundice and the development of liver fibrosis and cirrhosis. It requires early identification and prompt surgical management to try and forestall liver failure. The research database is required to continue to analyse the demographics and outcomes of all infants with biliary atresia, to continue to improve outcomes of infants and children with this disease. Data is collected by the direct care team in individual centres, and name is removed. At the end of each year, confidential patient information including hospital number, date of birth and gender and NHS number alongside a pseudo-Identifier and clinical information about each new patient treated in the centre for biliary atresia is transferred via a password-protected spreadsheet using NHS emails, to the central database (in KCH) together with a yearly record of outcome of all infants previously registered. These annual updates of patient management and outcome for previously registered children are then linked to baseline measures via the hospital ID. Data are stored on password-protected hospital server at KCH and only accessible by Mark Davenport, and a nominated deputy.

Confidential information requested

Cohort	All infants diagnosed with biliary atresia and managed in one of the three national centres, from January 1999 onwards Approximately 850 infants, and more prospectively.
Data sources	Medical records at the three national centres; • Kings College Hospital, London • Birmingham Women's and Children's Hospital • Leeds Children's Hospital
Identifiers required for linkage purposes (for annual follow up)	1. Hospital ID

Identifiers retained in registry	1. Hospital ID – to allow linkage 2. NHS number – as suggested by CAG (to ensure future linkage is possible if required) 3. DOB – to allow linkage and for analysis 4. Maternal Postcode – for analysis 5. Gender – to allow linkage and for analysis 6. Ethnicity – for analysis 7. Date of surgical (Kasai) intervention – for analysis 8. Clearance of jaundice – Primary outcome measure 9. Associated anomalies – for analysis 10. Type of BA – for analysis 11. Need for and date of transplant – for analysis 12. Date of death – for analysis
Identifiers required for analysis purposes	1. Maternal postcode (at time of childs birth) 2. Ethnicity, 3. Associated congenital anomalies, 4. Type of biliary atresia, 5. Date of surgical (Kasai) intervention 6. Date of liver transplant 7. Date of death 8. Date of Birth 9. Gender
Additional information	An update of patient management and outcomes for all previously registered children is also sent annually to KCH. These annual outcomes will cease once a child turns 16, but their previously collected data will remain in the registry

Confidentiality Group Advice

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

Number	Action required	Response from the applicant
1.	Please make the following changes to the notification documents: a. Please include the use of research on both the poster for adults, and children, and it should be made	The applicant made the proposed changes and CAG were content with these documents.

	clear that an individual can opt out of the research database separately from the non-research application if required. b. The CAG request that the National Data-Opt Out should be applied to research uses of the database, for extracts after 1st August 2022. This should also be made clear on the patient notification. c. Please simplify the poster for children further and provide back to CAG for review. Consider asking the PPI group for advice regarding this. d. Please confirm if you will be able to display some information about the application on the KCH website? e. Please confirm if leaflets can be developed from the content of the posters, to use for the clinical team in each participating trust to disseminate? f. Please clarify the point about data after the age of 16 on the notifications.	
2.	Please confirm there are safeguards in place for the database that reduce the reliance on the Chief Investigator.	The applicant confirmed ha has a deputy at Kings (consultant – Ms Erica Makin) who has access to the database and is regularly appraised of updates. There is also a steering Biliary Atresia Registry (BAR) committee made up of representatives from the three Trusts and the CLDF. Annual

		meeting arranged for March 7th this year in Birmingham with Ms Peng Ong (consultant surgeon) leading.) CAG was content with this update.
3.	Please confirm that the steering committee will assess each future research use as having an appropriate medical purpose.	The applicant confirmed this and CAG was content with the response.
4.	Please provide the Favourable opinion from the REC, as per standard condition of support.	This was provided in April 2023, as per standard condition of support
5.	Please provide the 21/22 DSPT reviews from NHS Digital for Kings College Hospital NHS Foundation Trust, Birmingham Women's and Children's NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust, as per standard condition of CAG support	The 22/23 DSPTs are currently in place, as per standard condition of support.

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.	Support will be provided for 5 years in the first instance. A duration amendment will be required at this time to ensure continuing 's251' support.
2.	Ongoing Patient and Public Involvement and Engagement is required to be undertaken and reported to CAG at annual review. This is specifically requested to focus on; a) The acceptability of this use of confidential patient information without consent.

	b) Their opinions on the level of confidential patient information retained; c) Feedback surrounding newly developed notification materials; d) The research uses of the database
3.	The NDOO is to be applied to any research use of the database for children included post 1st August 2022
4.	Favourable opinion from a Research Ethics Committee. **Confirmed 25 April 2023**
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 22/23 DSPT reviews for **Kings College Hospital NHS Foundation Trust, Birmingham Women's and Children's NHS Foundation Trust & Leeds Teaching Hospitals NHS Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 06 March 2024).

1.6	**23/CAG/0110**	**Royal Hospital for Neuro-disability (RHN) patients Database**
	Chief Investigator:	Mr Benedikt von Thungen
	Sponsor:	Sanome Ltd
	Application type:	Research Database

Also in attendance:

Name	Position (or reason for attending)
Mrs Emma Marshall	Confidentiality Specialist

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome.

Summary of application

This application from Sanome Limited sets out the purpose of medical research.

The RHN is a specialised hospital and medical charity treating adults with complex neuro-disabilities from both the NHS and private sector. This application proposes to collect patient data from all past patients who have been treated at the RHN into a research database for the purposes of conducting medical research. The database will be used to develop an early warning detection system to detect early signs of

health deterioration or improvement in patients. The database will also be used to develop tools to identify potential links between variables and patient outcomes.

Support is requested for the flow of confidential patient information from the electronic patient record (EPR) system (Patient Source) at RHN for Sanome Limited to pseudonymise the data and create a research database held within the Patient Source cloud environment. Support is also requested for Sanome Limited and researchers at RHN to access the database.

Confidential information requested

Cohort	All past patients who have been treated since implementation of electronic patient records at the Royal Hospital for Neuro-Disability*
Data sources	Electronic patient records held at the Royal Hospital for Neuro-Disability
Identifiers required for validation purposes	1.Year of birth 2.Date of death 3.Postcode (sector level) 4.Gender 5.Ethnicity 6.Free text and attachments forming part of a patient's medical record: • Nursing daily progress notes • HCA personal care record • Summary of nursing care • National Early Warning System 2 (NEWS2) actions Notes from other role types within the hospital e.g. physiotherapy notes
Identifiers required for analysis purposes	1.Year of birth 2.Date of death 3.Postcode (sector level) 4.Gender 5.Ethnicity 6.Free text and attachments forming part of a patient's medical record: • Nursing daily progress notes • HCA personal care record • Summary of nursing care • National Early Warning System 2 (NEWS2) actions Notes from other role types within the hospital e.g. physiotherapy notes
Additional information	*Number of past patients is 606

Confidentiality Advice Team Advice

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome 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.	The Research Ethics Favourable Opinion was issued on 4 March 2024, enabling support to be issued.

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.	Section 251 support is limited to 2 years from the date of the supported outcome letter
4.	Favourable opinion from a Research Ethics Committee. **Confirmed 04 March 2024**
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 **22/23** DSPT review for **RHN and Sanome Ltd and Patient Source** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (05 March 2024)

1.7	**24/CAG/0013**	**Wessex sub national secure data environment (SNSDE) programme**
	Chief Investigator:	Prof. Christopher Kipps
	Sponsor:	University Hospital Southampton NHS Foundation Trust

	Application type:	Research Database

Also in attendance:

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

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome.

Summary of application

This application, from University Hospital Southampton NHS Foundation Trust, sets out the medical purpose to create a research database.

University Hospital Southampton NHS Foundation Trust are developing the Wessex sub-national Secure Data Environment (SNSDE). This is part of a national initiative to move towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy.

The Wessex SNSDE will consist of two separate parts: the data processing environment (DPE) and the trusted research environment (TRE). Patient data will flow from each of the contributing organisations to the data processing environment, where it is checked, linked, de-identified, filtered, and transformed to produce a research database that can be used to produce extracts for research purposes. Data from each individual processing environment is only linked with data from other environments once an approved programme of research has been identified. A core dataset will be transferred to the SNSDE for use. Any data that sits outside the core dataset will only be transferred for research specific purposes once the research has been approved.

Support is requested for the flow of Confidential Patient Information from individual organisations within the Wessex SDE area to University Hospital Southampton NHS Foundation Trust, and retention within the SDE. Whilst the flow itself will be pseudonymised, University Hospital Southampton NHS Foundation Trust will have access to the keys to enable reidentification for specific purposes. Linkage to HES and SUS data is also requested, but this will only be undertaken on a per project basis only.

The SNSDE will be used for data-driven translational research in any field of health or social care. Research projects will be approved by a single, dedicated Data Access Committee (DAC). This committee will comprise lay members, alongside representatives from the participating healthcare organisations. The University Hospital Southampton's existing DAC will be used whilst the Wessex SNSDE is set

up. There is wider work ongoing at a national level to standardise and streamline the data access approach.

The SDE will be set up in stages, with specific datasets initially used to test the success of the linkage processes before moving to wider primary and secondar care organisations within the SDE footprint once success confirmed.

Confidential information requested

Cohort	All normally resident patients plus any patient accessing services in the Wessex area (Hampshire, Dorset and Isle of Wight ICBs) unless registered an opt out (approximately 2.7 million people).
Data sources	1. All primary and secondary care organisations within the Wessex SDE footprint 2. Specific datasets held by University Hospital Southampton NHS Foundation Trust: a. data from NIHR Health Informatics Collaborative (HIC), (Viral Hep: IRAS ID 289900, Myeloma: IRAS ID 310036, Cardio/COVID: IRAS ID 174052) b. data from ECRIN and IDX2 lung projects (IRAS ID 186109 and 283721 respectively) c. data for clinical trial feasibility assessments d. data from PRANA (IRAS ID 338740)
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID 3. Name 4. Address 5. Gender 6. Date of birth 7. Postcode 8. Date of death
Identifiers required for analysis purposes	1. Postcode (sector level) 2. Gender 3. Occupation 4. Ethnicity
Additional information	Whilst the flows of CPI will be pseudonymised to minimise risk during the transfer, University Hospital Southampton NHS Foundation Trust, will be able to identify the CPI. Whilst the applicants state that data source 4b is consented, the consent does not extend to use within the Wessex SDE.

Confidentiality Advice Team Advice

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome 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.	The Research Ethics Favourable Opinion was issued on 14 March 2024, enabling support to be issued.

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 March 2024**
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 **22/23** DSPT review for **University Hospital Southampton NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker

1.8	**23/CAG/0180**	**An analysis of the malignancy risk following Gamma Knife Stereotactic Radiosurgery**
	Chief Investigator:	Mr Julian Cahill
	Sponsor:	Sheffield Teaching Hospitals NHS Foundation Trust
	Application type:	Research

Also in attendance:

Name	Position (or reason for attending)

Ms Caroline Watchurst	HRA Confidentiality Advisor

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome.

Summary of application

This application from Sheffield Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to evaluate the risk of Gamma Knife Stereotactic Radiosurgery (GKSRS) treatment in causing malignant transformation of benign tumours, for the purposes of improving patient care. The results are expected by the applicant to be generalisable to the worldwide population of patients treated by GKSRS.

This activity has previously been undertaken twice by the Trust, once under Section 60 support between 2002-2005 (MR777), and most recently in 2016 under 'S251 support' (CAG ref 16/CAG/0009). The outcome from this project will further support the outcomes from those previous pieces of work.

Gamma Knife Stereotactic Radiosurgery (GKSRS) is used worldwide to treat several different pathologies in the head. Most of these are non-cancerous (benign) tumours or vascular malformations. As with any radiation treatment, there is a theoretical risk of the tumour becoming malignant or the treated area developing a new cancer as a response to the treatment. This project aims to evaluate the risk of malignant transformation, or induced malignancies, that could reasonably be attributable to the treatment of patients with Gamma Knife. There are many thousands of patients treated by the Gamma Knife worldwide every year and this risk is incredibly small. Large centres such as Sheffield, with many years of patient treatment data, are in a unique position to be able to accurately evaluate the real risk of this malignant development to aid accurate patient counselling and consent. This would improve patient care both in the UK and internationally as patients worldwide will benefit from strengthened and updated information on the real risk of malignant induction or transformation after radiation treatment for mainly benign disease.

's251' support is requested to allow the applicant to flow identifiable information about all patients treated by the National Centre for Stereotactic Radiosurgery, Sheffield, prior to 01 January 2023, to NHS England. NHS England will link the confidential patient information provided to Civil Registrations of Death dataset and Cancer Registrations dataset, and return the following information to the applicant - date of cancer diagnosis, cancer type and location, and date and cause of death.

Confidential information requested

Cohort	All patients treated before 01 January 2023 by the National Centre for Stereotactic Radiosurgery, Sheffield excluding those who have opted out of data usage. Approximately 17,400 patients
Data sources	1. Sheffield Teaching Hospitals NHS Foundation Trust - Radiosurgery Patient Database (STH GKSRS database), clinical database retained by direct care team (out of scope for 's251' support). 2. NHS England • Civil registration of deaths dataset • Cancer registration dataset
Identifiers required for linkage purposes	1. NHS Number 2. Gender 3. Date of Birth
Identifiers required for analysis purposes	1. Date of death – modified to survival times 2. Date of birth – did not answer if this would be modified for analysis, but I think it is 3. Gender

The Confidentiality Advice Team considered the applicant's response to the request for further information detailed in the provisionally supported outcome 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.	The Research Ethics Favourable Opinion was issued on 20 March 2024, enabling support to be issued.

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 clarify how many individuals participated within the patient and public involvement and engagement group discussions, and provide CAG with the questions asked to the engagement groups, particularly around the use of identifiable patient information without consent. The CAG request for these details to be provided to CAG within the next 6 months.
2.	Favourable opinion from a Research Ethics Committee. **Confirmed 20 March 2024**
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 **22/23** DSPT reviews for **NHS England & Sheffield Teaching Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 15 December 2023)

1.9	**24/CAG/0015**	**The Rituals of Integrated Working: Promoting and Improving Integrated Care**
	Chief Investigator:	Dr Jenelle Clarke
	Sponsor:	University of Kent
	Application type:	Research

Present:

Name	Capacity
Dr Murat Soncul	Alternate Vice Chair
Dr Pauline Lyseight-Jones	CAG Lay Member
Mr Dan Roulstone	CAG Lay Member

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 detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from University of Kent set out the purpose of medical research that seeks to explore how, and to what extent, everyday interactions promote or hinder integrated working, in integrated health care, including mental health services, acute services and community health services. Interactions can include activities such as meetings, informal conversations and/or clinical group discussions.

Bringing together services is often when different agencies, such as mental health and social care, join up to coordinate care around patient needs. This is sometimes referred to as 'joined up' or 'integrated care'. However, bringing together services can be very difficult. Different organisations and teams operate differently, and there can be confusion, and sometimes tension, around who will do what, who will pay for it, and who has access to certain types of information. Staff and service users/carers often try to resolve these difficulties through meetings and visits. Unresolved challenges can result in poorer patient care. This study looks at what it is like to deliver and receive joined up care. It focuses on how different groups of people come to trust each other and work collaboratively through everyday encounters. Learning from this study will help improve integrated care services.

A researcher is undertaking a number of different methodologies at 4 participating Trusts, including consented staff and patient interviews and focus groups, and further work as part of work packages 2, 3 and 4. These elements do not require 's251' support.

However as part of Work Package 1, the researcher, who is not considered direct care team, is also undertaking ethnographic observations of the interactions and relationships that enable integrated and multidisciplinary working of Health care professionals working in integrated care. These include professional interactions conducted in the course of care away from patients, for example, board rounds, ward round briefings and wrap ups, referrals and Multi-Disciplinary Team (MDT) meetings, as well as informal conversations between professionals. 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. Identifiable patient information will not be recorded. The researcher will conduct staff observations for six weeks at the research sites to understand situated practices and interaction rituals (6 months total).

Confidential information requested

Cohort	Patients over the age of 16, who are under the care of participating integrated health service teams, who are discussed during staff member interactions during routine clinical discussions and team meetings, and have not provided consent. Very approximately 30 patients per team - 120 overall. Over 6 months of observations
Data sources	Clinical meetings/observations in the following participating Trusts: • Derbyshire Healthcare NHS Foundation Trust • Kent Community Health NHS Foundation Trust • Kent and Medway NHS Social Care Partnership Trust • Lincolnshire Community Health Services NHS Trust
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

Confidentiality Group Advice

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

#	**Action required**	**Response from the applicant**
1.	Please provide detailed feedback on exactly what was discussed with the PPI group, specifically whether representatives were supportive of this use of identifiable data without consent.	The applicant attached a summary of what was discussed with the PPI Group. Please note that in the most recent meeting where the group discussed CAG feedback, the group advocated for creating a generic poster to be printed on poster size paper (at least A3 but larger if clinics can accommodate a larger size), for patients and carers to understand that

		research does occur in their respective service. It is hoped that patients may be more likely to read a generic poster and ask about research studies, including this one, in order to find out more information to opt out. **This generic poster does not replace the patient notification poster, as both would be displayed.** The CAG were content with the response.
2.	Please update the patient notification materials as follow and provide to CAG for review: a. Proofread and make it clear and easy to understand. b. Please ensure the breach of confidentiality is clearly described – ie. Dr. Clarke (who is not part of your direct care team) might hear identifiable information about you and your care, whilst undertaking observations of clinical interactions. No identifying information will be recorded, and patient information is not the reason for observing	a. The patient notification has been proof read and changes are highlighted in yellow. b. The breach of confidentiality is clearly described. The PPI Group recommended some minor adjustments to your suggested text (i.e. switching up some of the information presented), but is otherwise as suggested. All changes have been highlighted in yellow. The CAG were content with this 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 02 January 2024**

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 **22/23** DSPT reviews **for Derbyshire Healthcare NHS Foundation Trust, Kent Community Health NHS Foundation Trust, Kent and Medway NHS Social Care Partnership Trust & Lincolnshire Community Health Services NHS Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 22 March 2024)

1.10	**24/CAG/0034**	**North West Sub National Secure Data Environment: Greater Manchester ICB**
	Chief Investigator:	Mr Matt Hennessey
	Sponsor:	NHS Greater Manchester Integrated Care Board (ICB)
	Application type:	Research Database

Also in attendance:

Name	Position (or reason for attending)
Emma Marshall	Confidentiality Specialist

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from Greater Manchester Integrated Care Board (GM ICB) sets out the medical purpose to create a create a research database.

Greater Manchester ICB are developing the Northwest sub-national Secure Data Environment (SNSDE). This is part of a national initiative to move towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy. SNSDEs across the country will also become interoperable to enable access. Further details on this national initiative and progress to date is here. Note that the Northwest SDE is using a federated approach and each ICB in the North West is submitting separate applications (Cheshire and Merseyside ICB in this meeting, and Lancashire and Cumbria at a later date).

GM ICB are linking data from multiple sources to create a deidentified dataset for research use. Support is requested for Graphnet to pseudonymise the local shared care record and share with Arden and GEM CSU (processing on behalf of GM ICB), for Arden and GEM CSU to pseudonymise civil registrations and deaths for use in

the SDE, and for local organisations to share identifiable information to GM ICB, where they are unable to pseudonymise at source. Other national sources are shared under Directions, or pseudonymised at source and are outside the scope of CAG. Support is also requested for the retention of confidential patient information within the SNSDE environment.

Requests for data access are governed by the Data Access Committee (DAC), who are advised and informed by the Application Review Group (ARG). The ARG contained 2 public members. The DAC make the final decision, based on advice received by the ARG. Whilst this is currently specific for GM ICB, there are plans to consolidate to have one data access route in the Northwest.

Confidential information requested

Cohort	The registered and resident population of Greater Manchester and the individuals who have received care at the providers within Greater Manchester.
Data sources	1. Local Shared Care record (GP data via Graphnet) 2. Data sources processed by Data Service for Commissioners Regional Office (DSCRO) at Arden and GEM CSU a. Alcohol Dependence b. Ambulance Data c. Assuring Transformation (learning disabilities) d. Community Services Dataset e. Clinical Audits and Registries f. Continuing Health Care g. CVD Prevent h. Diagnostics Imaging Dataset i. e-referral system dataset j. Faster Data Flows k. Maternity Services Dataset l. Medicines dispensed in primary care m. National cancer waiting times n. NHS Pathways Dataset (111/999) o. Patient reported outcomes dataset (PROMS) 3. National Data Sources processed by Data Service for Commissioners Regional Office at Arden and GEM (CSU) a. civil registrations - births b. civil registrations - deaths 4. National Data Sources covered under the national NHS Direction from health and social care for use for research (described in section 2.2.2 of the protocol)

	5. Local organisation data a. Pseudonymised at source b. Unable to be pseudonymised at source
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode
Identifiers required for analysis purposes	1. Year and quarter of birth 2. Year and month of death 3. Gender 4. Ethnicity 5. Lower Super Output Area

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome 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.	The Research Ethics Favourable Opinion was issued on 20 March 2024, enabling support to be issued.

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.	Clarify whether organisations that are unable to pseudonymise at source will flow information to Greater Manchester ICB or Arden and GEM Commissioning Support Unit (CSU).
2.	Provide a summary on whether there were any changing attitudes that had resulted in a change of approach at first annual review.

3.	Investigate whether notification or signposting to the study can added onto the NHS app and provide an update at first annual review.
4.	Favourable opinion from a Research Ethics Committee. **Confirmed 27 March 2024**
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: 27 March 2024** The NHS England **2023/24** DSPT review for NHS Greater Manchester Integrated Care Board, Arden and GEM CSU and Snowflake Computing UK Limited was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 27 March 2024)

1.11	**24/CAG/0026**	**Assembling the data jigsaw: MSK research using linked social care data**
	Chief Investigator:	Professor Will Dixon
	Sponsor:	University of Manchester
	Application type:	Research

Present:

Name	Capacity
Mr Anthony Kane	CAG Lay Member
Dr Pauline Lyseight-Jones	CAG Lay Member
Mrs Sarah Palmer-Edwards	CAG Expert Member
Mr Dan Roulstone	CAG Lay Member
Ms Clare Sanderson	CAG Alternate Vice Chair

Also in attendance:

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

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome and line with the CAG considerations in correspondence.

Summary of application

This application from the University of Manchester set out the purpose of medical research that seeks to understand the number of patients with musculoskeletal conditions accessing social care and the types of social care accessed.

People with musculoskeletal (MSK) conditions often experience pain and reduced physical function as symptoms of their condition. Reduced function and its effects on activities of daily living and wellbeing can be a driver of demand for social care services, particularly for services involving personal care, such as home care. It can also be a driver for support from family and friends ('informal' social care). However, the proportion of adults with chronic MSK pain accessing social care services is not known. The applicants will undertake analysis of linked data on retrospective cohorts of individuals receiving hospital outpatient NHS and Adult Social Care contact over one year, between 1 January to 30 December 2022.

Secondary care data provided by the Northern Care Alliance NHS Foundation Trust (NCA) will be disclosed to Salford Council for linkage to Adult Social Care (ASC) data. NCA will extract NHS numbers and dates of birth for patients with Rheumatoid Arthritis (RA) who have attended a hospital outpatient clinic at the Trust during 2022. NCA will create a unique identifier for all patients in the dataset and add this to the NHS numbers and dates of birth. This list will be transferred to Salford Council via MESH. Salford City Council will extract ASC data for patients found in their system. The ASC extract will include NHS number, DOB and Unique identifier. Salford City Council will remove and delete the NHS number from the list retaining only DOB and unique identifier. Salford City Council will upload this ASC dataset (with DOB and unique identifier) to MESH. NCA will pull down the ASC dataset and link it to the extract of hospital outpatient data. The linked dataset will be de-identified and made available to the research team.

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

Confidential information requested

Cohort	Patients aged 18 years and over with a long-term condition, including musculoskeletal diagnosis, who attended a hospital outpatient clinic at the Trust during 2022.
Data sources	1. Secondary care data, Northern Care Alliance NHS Foundation Trust 2. Social Care data, Salford City Council

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Ethnicity

Confidentiality Group Advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome 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.	The REC Favourable Opinion was confirmed on 07 February 2024.
2.	Security assurances for 2022/23 are outstanding for the following organisations. • *Salford City Council* Please contact NHS England at exeter.helpdesk@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 confirmed.
3.	Provide a clear explanation as to whether the cohort includes patients attending any outpatient clinic or only patients attending outpatient clinics related to musculoskeletal conditions.	The applicants confirmed that only patients attending a specific Rheumatology outpatients clinic will be included. The CAG noted this information and raised no further queries.
4.	Confirm the dates for inclusion and the specific support	The applicants confirmed that patients attending adult rheumatology

	requested	outpatients clinic between June 2013 and September 2021 and adult service users in receipt of Adult Social Care services from Salford Council between January and December 2022 will be included. The support sought is to link these two datasets, one from NHS rheumatology clinic and one from Salford Council Adult Social Care, to estimate the numbers of patients attending rheumatology clinic who are also users of social care services from the Council. The CAG noted this information and raised no further queries.
5.	Provide a clear explanation on the adult social care data to be processed under Section 251 support and whether it included free text or structured data.	All the adult social care data to be processed will include structured data only. These are data currently collated by the council under the Client Level Adult Social Care Data (No 3) Directions 2023, for national reporting. The data will include: • receipt of, e.g. number of visits per week of: - Home ('domiciliary') care - Day care - Social work support - Care homes • Whether or not they have an informal carer • Whether or not they require help with the following activities of daily living: • Managing and maintaining nutrition (eating and drinking). • Maintaining personal hygiene (washing, bathing). • Managing toilet needs (using the toilet, managing bladder or bowels). • Being appropriately clothed. • Maintaining a habitable home environment (keeping home clean, safe and secure). • Being able to make use of the home safely (moving around

		inside, getting in and out of home, using stairs) • Primary Support Reason (reasons in mandated Care Act National Eligibility Criteria). See list of data items below. The CAG noted this information and raised no further queries.
6.	Provide explanation on what will happen to patients' date of birth after receipt. If the date of birth is going to be retained for secondary linkages, justification needs to be provided.	Date of birth will no longer be used for linkage. The linkage key will be NHS number and a newly generated participant ID created by the Northern Care Alliance. Please advise if the CAG application should be updated with this revised linkage method. NCA = Norther Care Alliance NHS Trust SCC = Salford City Council 1. NCA will create an identifier file containing NHSs and newly created participant IDs 'participant ID'. 2. NCA share the identifier file with SCC. 3. SCC use the identifier file to extract ASC data for the research cohort, creating an ASC research dataset also containing the NHS number and participant ID. 4. SCC remove the NHS number from the ASC research dataset leaving the ASC data plus the participant ID. 5. SCC will destroy the NHS number. 6. SCC will transfer back to NCA only the ASC research data plus participant ID. The CAG noted this information and raised no further queries.
7.	Clarify whether the research team have explored the use of confidential patient information without consent with the Patient and Public Involvement group. If	A workshop was held with the PPI group, where the NHS opt-out was explained and why specific consent for this research was not being sought. The applicants also discussed the

	so, please provide the queries asked and feedback given. If not, further specific patient and public involvement needs to be undertaken with a sub-group, to discuss the use of confidential patient information, without consent, for the purpose of this application. Feedback from the discussion is to be provided to the CAG.	additional opportunity to opt out of this study and worked through the proposed notification, incorporating suggestions from the PPI group as to where to best display this as well as wording changes. All participants fully supported the use of their data being linked and used for this specific research without explicit consent once we explained how their data would be held safely and securely with controlled access. The CAG noted this information and raised no further queries.
8.	Update the patient notification materials as follows and provide to CAG for review: a. Amend all the publicly available information to reflect the slippage or extension of the work. b. Update the patient notifications to explain how a patient can request the removal of their data via local opt-out. c. The notifications need to be made available at least 6 weeks prior to when any data is extracted so the patients can be advised to opt-out if they wish. d. Further methods of patient notification also need to be developed, adopting a layered approach, making information available in brief accessible posters for relevant clinical areas as well as online. e.	An updated patient notification document was provided, which was 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 07 February 2024**
2.	The NHS England 2022/23 DSPT review for **Northern Care Alliance NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 27 March 2024).

2. NEW AMENDMENTS

2.1	**18/CAG/0182**	**UK Prospective Diabetes Study (UKPDS) Legacy Study: long term follow-up of participants into electronic health records**
	Chief Investigator:	Professor Rury R. Holman
	Sponsor:	University of Oxford
	Application type:	Research

Present:

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice-Chair

Also in attendance:

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

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

Summary of amendment request

This application aims to undertake longitudinal follow-ups of participants within in the UK Prospective Diabetes Study (UKPDS). This original study ran from 1977 and 1997. ‘s251’ support is in place for linkage with outcome data.

This amendment sought to extend the duration of ‘s251’ support to October 2028, to allow further time to complete the linkages with outcome data.

This amendment also sought support for University of Oxford to flow confidential patient information (UKPDS Identifier, first name or Initial, Surname, date of birth, sex, postcode – (where known), Hospital No. (Belfast Health and Social care Trust), and date of death – (where known)) to the Belfast Health and Social care Trust, for the purposes of linking to North Irish outcome data. This flow requires ‘s251’ support, however any processing in Northern Ireland is out of scope for ‘s251’. The applicants have the appropriate permissions in place in Northern Ireland.

Confidentiality Advisory Group advice: Fully supported

The amendment requested was considered by Chair’s Action. The Alternate Vice-Chair was content to recommend support for this amendment.

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 22/23 DSPT reviews for **University of Oxford - Medical Sciences Division - Nuffield Department of Population Health & NHS England** were confirmed as ‘**Standards Met’** on the NHS England DSPT Tracker (checked 15 February 2024)
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 08 February 2024**

2.2	**21/CAG/0123**	**RE-BLEED: A digital platform for identifying bleeding patients – a feasibility study**
	Chief Investigator:	Professor Peter Watkinson
	Sponsor:	University of Oxford
	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 amendment in line with the CAG considerations in correspondence.

Summary of amendment request

This application to test whether a digital platform can efficiently identify patients who have suffered a bleeding event, has 's251' support to allow members of the research team to access confidential patient information for patients identified as having met the study criteria, so that patients can be approached for consent.

This amendment sought support to extend the duration of 's251' support until 28 February 2025, to allow the applicant to complete sub-group analyses.

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 **22/23** DSPT review for **Oxford University Hospitals NHS Foundation Trust** is confirmed (by check of the NHS England

	DSPT tracker on 08 March 2024)
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 13 February 2024**

2.3	**22/CAG/0049**	**LOng COvid Multidisciplinary consortium: Optimising Treatments and servIces across the NHS (LOCOMOTION)**
	Chief Investigator:	Dr Manoj Sivan
	Sponsor:	University of Leeds
	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 amendment in line with the CAG considerations in correspondence.

Summary of amendment request

This application aims to find out the most effective rehabilitation treatment for Long Covid (LC) currently being delivered across ten UK-wide LC clinics.

This amendment sought to extend the duration of 's251' support until 30 June 2024, due to delays in processing the data.

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 the data controller, to ensure that participating organisations meet the minimum required standard in complying with DSPTs, (or Welsh IG toolkits) 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 non substantial 14 December 2023**

2.4	**23/CAG/0072**	**Listen2Baby - Improving monitoring of the baby during uncomplicated labour: a study using experience-based co-design**
	Chief Investigator:	Associate Professor Rachel Rowe
	Sponsor:	University of Oxford
	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 amendment in line with the CAG considerations in correspondence.

Summary of amendment request

This application aims to improve the quality and safety of fetal monitoring in uncomplicated labours through an improved understanding of the organisational context and practice of intermittent auscultation (IA) during labour, and ultimately improve care for women and babies, by the development and initial evaluation of a 'toolkit' to improve IA practice. ‘S251’ support is in place to allow confidential patient information to be viewed by a University of Oxford researcher, who is not considered part of the direct care team, during the extraction of an effectively anonymised dataset for analysis, and to allow for incidental exposures of confidential patient information that may occur when the researcher is undertaking observations of relevant clinical meetings at participating sites.

This amendment sought to include Gloucester Hospitals NHS Trust as a participating site, and additional data processor for the application under ‘s251’ support.

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 participating 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.
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 19 February 2024**

2.5	**22/CAG/0137**	**West Yorkshire ICB S251 non-research**
	Contact:	Mrs Natalie Tolson
	Data controller:	West Yorkshire Integrated Care Board (ICB)
	Application type:	Non-research

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair

Also in attendance:

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

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

Summary of amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating GP practices to North of England Commissioning Support Unit (NECS) and disclosure of confidential patient information from NHS England to NECS, and the continued holding of confidential patient information by NECs and the holding of the linked dataset by West Yorkshire Integrated Care Board.
This clarification amendment sought to ensure that CAG are aware that data collected from GP practices for this application will also cover any other services developed (within Primary Care Networks (PCN - groups of GP Practices)/GP practices). As PCNs develop there is a growing requirement to collect additional clinical data fields to support specific primary care focused direct healthcare interventions with patients. This is to evaluate certain direct healthcare interventions to understand their effectiveness by linking with existing commissioning datasets. The identifiers for extraction are already agreed under the existing 's251' support. However, there may be unique non identifiable data items required for individual primary care focused healthcare interventions as they are implemented.

The clarification to 's251' support is the principle that the applicants may have new services that they wish to include which they might need bespoke clinical data for, and they want to ensure that any developments are within the terms of 's251' support.

- There is no change to data sources (as data sources are still the GP practices. However for the PACT service specifically, the data is on a spreadsheet rather than through SystmOne, but still is data from the GP practices).
- There is no change to data flows (aside from the mentioned bypassing of SytsmOne in this case)
- There is no change to the identifiers accessed. Additional non identifiable data items (such as grip test) will be collected.

Confidentiality Advisory Group advice: Fully supported

The amendment requested was considered by Chair's Action. The Chair recommended support for this clarification amendment, however noted that any material changes to data flow, processing or new data items will be dealt with via amendment to CAG in the usual manner, ie. if a new service is introduced where there is additional processing of identifiers, that would require an amendment to 's251' support.

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 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 **22/23** DSPT reviews for **NHS England** and **The North of England Commissioning Support Unit (NECS)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 07 March 2024) Due to the number of GP Practices involved it is the responsibility of the data controller, to ensure that practices 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 a practice.

2.6	**23/CAG/0105**	**Lancashire and South Cumbria Integrated Care Board (ICB) -Disclosure of combined commissioning data sets and GP data for risk stratification purposes to Integrated Care Boards and Data Processors**
	Contact:	Asim Patel
	Data controller:	Lancashire and South Cumbria Integrated Care Board (ICB)
	Application type:	Non-research

Also in attendance:

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

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

Summary of amendment request

This application is to allow Lancashire and South Cumbria Integrated Care Board (ICB) to undertake risk stratification on their population. Support was in place to allow NHS Midlands and Lancashire Commissioning Support Unit to process confidential patient information as a risk stratification supplier for the ICB.

This amendment sought support to include Prescribing Services Limited (PSL) as an additional Risk Stratification provider, and additional data processor to this CAG application.

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 **22/23** DSPT reviews for **NHS Midlands and Lancashire Commissioning Support Unit & Prescribing Services Limited (PSL)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 08 March 2024)

2.7	**23/CAG/0095**	**Non-statutory Medical Examiner System – second phase in Wales**
	Contact:	Mr Andrew Evans
	Data controller:	NHS Wales Shared Services Partnership
	Application type:	Non-research

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair

Also in attendance:

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

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

Summary of amendment request

The applicants have existing support to allow the disclosure of confidential patient information for deceased patients, who were cared for by other healthcare providers, such as GPs, independent healthcare providers, and NHS Wales health boards which do not host a medical examiner office, to the medical examiners within host NHS Wales health boards.

Support under Regulation 5 was sought to provide a legal basis for this activity until primary legislation was introduced to put the system on a statutory footing. This was expected to be in place from 31 March 2024.

The applicants are seeking to extend the duration of support until 30 September 2024, as the primary legislation is not yet in place. The Department of Health and Social Care have advised that they do not expect the statutory system to be in place before the current 's251' support expires. Therefore, the applicants seek support until 30 September 2024 in case of further delays.

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 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** Due to the number of organisations involved it is the responsibility of the data controller, to ensure that Welsh Health boards hosting the medical examiners meet the minimum required standard in complying with the Welsh IG toolkit, and take remedial action if they

	become aware of any that fall below this, or where any concerns are raised about a Trust.

2.8	**23/CAG/0070**	**North Central London Integrated Care System (NCL ICS) application for secondary use of data**
	Contact:	James Tyler
	Data controller:	NHS North Central London (NCL) Integrated Care Board
	Application type:	Non-research

Present:

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair

Also in attendance:

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

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

Summary of amendment request

This application has ‘s251’ support in place to allow the processing of confidential patient information by NHS North Central London (NCL) Integrated Care Board/ Integrated Care System (ICB/ICS) analysts, and Cerner Limited, during the linkage of the NCL ICB direct care data platform (HealtheIntent) to NHS England national datasets, for the purposes of creating a new dataset to be used for non-research secondary purposes, such as population health management (PHM), risk stratification, and planning and analysis, regarding the North Central London population.

This amendment sought support to clarify that the linkage to NHS England national datasets would be phased in throughout the first year of ‘s251’ support. The applicant intends to first build a segregated NCL Population Health system tenancy (also known as HealtheIntent) for the same purposes described in the application, using only local controller identifiers (from NCL’s GP, NHS Trusts and Local Authorities) before, at a later stage linking to the national/ICB data sets, as is already supported. This amendment is to clarify those plans, and confirm that ‘s251’ support remains in place

to cover the processing described, prior to linkage with NHS England data, and to continue to allow the processing of confidential patient information by NHS North Central London (NCL) Integrated Care Board/ Integrated Care System (ICB/ICS) analysts, and Cerner Limited, during the processing of the NCL ICB direct care data platform (HealtheIntent), for non-research secondary purposes, such as population health management (PHM), risk stratification, and planning and analysis, regarding the North Central London population.

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 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 **22/23** DSPT reviews for **ORACLE CORPORATION UK LTD, Amazon Web Services, and North Central London Integrated Care Board** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 12 March 2024)

2.9	**21/CAG/0032**	**Non-statutory Medical Examiner System – second phase**
	Contact:	Mr Nick Day
	Data controller:	NHS England
	Application type:	Non-research

Present:

Name	Capacity
Dr Tony Calland, MBE	CAG Chair

Also in attendance:

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

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

Summary of amendment request

The applicants have existing support to allow the disclosure of confidential patient information for deceased patients, who were cared for by other healthcare providers, such as GPs, independent healthcare providers, and NHS Trusts and NHS foundation trusts which do not host a medical examiner office, to the medical examiners within host NHS trusts.

Support under Regulation 5 was sought to provide a legal basis for this activity until primary legislation was introduced to put the system on a statutory footing. This was expected to be in place from April 2022. Two previous amendments have been supported to extend the duration of 's251' support, and support is currently in place until 31 March 2024.

The applicants are seeking to extend the duration of support until 30 September 2024, as the primary legislation is not yet in place. The Department of Health and Social Care have advised that they do not expect the statutory system to be in place before the current 's251' support expires. Therefore, the applicants seek support until 30 September 2024 in case of further delays.

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 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**

	Due to the number of organisations involved it is the responsibility of NHS England and NHS Improvement, as controller, to ensure that Trusts hosting the medical examiners 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 a Trust.

2.10	**22/CAG/0105**	**Improving patient outcome in the 'hot zone' during a major incident: a mixed methods medical research approach**
	Chief Investigator:	Dr Claire Park
	Sponsor:	Barts Health NHS Trust
	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 amendment in line with the CAG considerations in correspondence.

Summary of amendment request

This application seeks to investigate the causes and timeline associated with pre-hospital death following terrorism incidents, and the pre-hospital interventions associated with decreasing pre-hospital mortality. ‘s251’ support is in place to allow the disclosure of confidential patient information from the London Ambulance Service and London Air Ambulance to HM Coroner Services in London and the Metropolitan Police (MPS) for linkage to their datasets, and the disclosure of a linked dataset to the Metropolitan Police Service (MPS).

This amendment sought to extend the duration of ‘s251’ support until 31 March 2025, to account for delays at the beginning of the project.

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 22/23 DSPT reviews for **London's Air Ambulance (part of Barts Health NHS Trust), The London Ambulance Service NHS Trust, Queen Mary University London (QMUL)** and **The Metropolitan Police (MPS)** (the applicant confirmed via email that the DSPT for MPS also covered HM coroner reports) were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 11 March 2024)
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non-substantial 15 March 2024**

2.11	**22/CAG/0103**	**Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services**
	Chief Investigator:	Professor Eileen FS Kaner
	Sponsor:	Newcastle 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 amendment in line with the CAG considerations in correspondence.

Summary of amendment request

The applicants have existing support to allow research staff at participating trusts to access confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. Hospital records will be accessed to determine the number of smokers who have been offered and used tobacco dependence services

and to calculate the cost of providing the service.

This amendment sought to extend the duration of 's251' support, as the funding organisation (NIHR) has provided a 15-month extension to the project, resulting in the new project end date moving from 31 March 2024, to 30 June 2025.

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 Newcastle University, 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 non substantial 29 February 2024**

2.12	**22/CAG/0010**	**The Integration and Analysis of Data Using ARtificial InTelligence to Improve Patient Outcomes with Thoracic Diseases**
	Chief Investigator:	Professor Fergus Gleeson
	Sponsor:	Oxford 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 amendment in line with the CAG considerations in correspondence.

Summary of amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating trusts to the Oxford University Hospitals NHS Foundation Trust, for the purposes of developing an Artificial Intelligence model to aid in the diagnosis of lung cancer in pulmonary nodules identified on CT scans performed as part of the NHSE Lung Cancer Screening Programme. Support is also in place to include national datasets from NHS England as additional data sources to ensure accurate outcome data.

This amendment sought support to extend the duration of 's251' support until 31 March 2025.

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 **2022/23** DSPT reviews for **Oxford University Hospitals NHS Foundation Trust**, **Oxford University** & **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 13 March 2024). Due to the number of participating sites where confidential patient information will be accessed, 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 non substantial 22 January 2024**

2.13	**16/CAG/0048**	**LATTE: Long-term Anastrozole vs Tamoxifen Treatment Effects**
	Chief Investigator:	Professor Jack Cuzick
	Sponsor:	Queen Mary University of London

	Application type:	Research Database

Also in attendance:

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

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

Summary of amendment request

The LATTE database collects follow up information on participants in the ATAC study (under consent given for that study). ATAC was a randomised, double-blind trial comparing Arimidex alone with Nolvadex alone with Arimidex and Nolvadex in combination as adjuvant treatment in post-menopausal women with breast cancer. The study team have previously accessed information from physicians collected as part of routine clinical care, with the consent of the participants. The applicants have 's251' support to supplement this data with linked outcome data from NHS England, due to missing follow-up data from participating sites. In 2019, an amendment was supported to continue collecting linked data from central sources only (NHS Digital at the time), and subsequently the study has closed all participating sites from 2019 onwards.

This amendment sought 's251' support to continue to collect linked outcome data from NHS England for the next five-year period, in line with their 5 year research database resubmission with the REC. Essentially extending the duration of 's251' support until 25 February 2029.

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 22/23 DSPT reviews for **Bart's Cancer Centre and NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 14 March 2024)
2.	Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 15 February 2024**

2.14	**23/CAG/0024**	**National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH**
	Contact:	Professor Louis Appleby
	Data controller:	Healthcare Quality Improvement Partnership (HQIP) and NHS England
	Application type:	Non-research

Also in attendance:

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

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

Summary of amendment request

The National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH) has support to collect confidential patient information for the NCISH core database on patients who died by suicide when under the recent care, or recently discharged from, specialist mental health services. 's251' support is in place specifically to allow the disclosure of confidential patient information from the Office for National Statistics to NCISH, University of Manchester, the onward disclosure to the treating healthcare organisation, and the return of the completed questionnaire to NCISH.

This amendment sought support to extend the duration of 's251' support until 31 March 2027.

The applicant also informed CAG of minor updates to the questionnaire for the real-time data collection of suspected suicide deaths by people under the recent care of mental health services in England, although these updates did not involve any changes to 's251' support. Applicants have also provided CAG with an updated protocol. These have been accepted as notifications only.

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 **2022/23** DSPT review for **National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH), University of Manchester** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 March 2024).

2.15	**19/CAG/0145 (previously CR9/2014)**	**Transfusion Medicine Epidemiology Review**
	Contact:	Miss Jan Mackenzie
	Data controller:	University of Edinburgh
	Application type:	Non-research

Also in attendance:

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

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

Summary of amendment request

This application is a public health surveillance review to determine whether Creutzfeldt–Jakob is transmissible through blood transfusion. 's251' support is in place to allow confidential patient information to be disclosed from NHS Blood and Transplant Services and the Welsh Blood Service to National CJR Research and Surveillance Unit (NCJDRSU) at the University of Edinburgh, for the team to link outcome data via NHS England.

This amendment sought to extend the duration of 's251' support until 31st March 2025. The amendment also sought support to include ARROW (previously called AIMES), as an additional data processor for the application. The data is now being held in a different secure location. This change occurred on 22nd June 2020. The data is now stored at ARROW (previously called AIMES). The previous location, the University of Edinburgh data safe haven, was unable to provide a key service that was required for the NCJDRSU, and is now closed down. The University of Edinburgh still processes the data when it arrives at the NCJDRSU and is added to the TMER database, so the University of Edinburgh also remain a data processor for the application.

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 **22/23** DSPT reviews for **NHS Blood & Transplant, Arrow Business Communications Ltd** (previously Aimes - 8J121) **NHS England**, and **University of Edinburgh (NCJDRSU)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 March 2024)

2.16	**CAG 5-07(d)/2013**	**National Emergency Laparotomy Audit (NELA)**
	Contact:	Sharon Drake
	Data controller:	Healthcare Quality Improvement Partnership (HQIP) and NHS England
	Application type:	Non-research

Also in attendance:

Name	Position (or reason for attending)

Ms Caroline Watchurst	HRA Confidentiality Advisor

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

Summary of amendment request

The National Emergency Laparotomy Audit (NELA) was set up in 2012 in response to a high incidence of death and wide variation in the provision of care and mortality for patients who receive emergency laparotomy (abdominal surgery) in England and Wales. NELA is delivered under contract to the Healthcare Quality Improvement Partnership (HQIP) by the Royal College of Anaesthetists and the Clinical Effectiveness Unit of the Royal College of Surgeons of England.

A previous amendment has been supported to add a new group of patients with pathologies indicative for emergency laparotomy but who do not undergo surgery (the 'no-lap' cohort). This amendment is to inform CAG of the full question set of data to be collected on this cohort, which was not available at the time of the amendment to include the no-lap cohort. This dataset includes the same items of confidential patient information as supported for the rest of the NELA cohort. It also includes other clinical items. The amendment also sought support to inform CAG of annual changes to the main NELA dataset, in the form of additional questions;

- What was the patient's preoperative delirium score using the 4AT tool?
- Is the patient known to have diabetes?
- What was the most recent blood glucose (Mmol/L) (venous, arterial or capillary (BM)?
- What was the patient's postoperative delirium score using the 4AT tool within 72 hours of transfer to a general surgical ward?

These additional questions do not involve additional processing of confidential patient information, and therefore has been accepted as a notification to CAG only.

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 22/23 DSPT reviews for **Royal College of Anaesthetists, Royal College of Surgeons of England, ANS Group Limited (as now merged with UKFAST)** & **NHS England,** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 13 March 2024).

2.17	**PIAG 4-08(b)/2003**	**National Confidential Enquiry into Patient Outcome and Death**
	Contact:	Dr Marisa Mason
	Data controller:	Healthcare Quality Improvement Partnership (HQIP) and NHS England
	Application type:	Non-research

Present:

Name	Capacity
Professor William Bernal	CAG Alternate Vice Chair

Also in attendance:

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

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

Summary of amendment request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes every year. This amendment covered the second of the reviews due to take place for 2023, which will identify and

explore the avoidable and modifiable factors in the care of adults with extreme levels of sodium in hospital.

Sodium levels in the body are usually carefully controlled. A number of conditions can lead to extremes of sodium levels that the body cannot adjust for which requires corrective action. If high levels of sodium levels fall too quickly the brain can swell (cerebral oedema) and this can lead to loss of consciousness, seizures and ultimately death. Conversely if very low sodium levels rise too quickly the brain can shrink, which can lead to an intracranial catastrophe. Moreover, correcting sodium levels too quickly can lead to a devastating irreversible locked-in syndrome called Osmotic Demyelination Syndrome (ODS) which is preventable if managed in the right clinical setting with the appropriate expertise. Therefore, managing alterations in sodium concentrations can be complex and challenging.

The applicants aim to publish the results of the review in late 2025.

Confidentiality Advisory Group advice: Fully supported

The amendment request was considered by Chair's Action. The Alternate Vice-Chair agreed that the amendment request was a straightforward amendment for NCEPOD to use its well-established methods to audit blood sodium as part of its regular programme, noting it was not an amendment of the methodology, but of the clinical work being audited. The Alternate Vice-Chair commented that NCEPOD is very well-established as one of the most effective audits undertaken in the UK, and was content to recommend support.

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 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 22/23 DSPT review for National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was confirmed as 'Standards Met' on the NHS England DSPT Tracker (by check of the NHS England DSPT Tracker on 13 March 2024)**

3. ANNUAL REVIEWS SUPPORTED

CAG reference	Title
19/CAG/0001	National Respiratory Audit Programme (NRAP): children and young people asthma audit
22/CAG/0012	Using linked secondary and primary care electronic health records to evaluate opioid utilisation and safety
18/CAG/0182	UK prospective diabetes study (UKPDS) legacy study: long terms follow up of participants into electronic health
14/CAG/1040	UCL Infection DNA Bank
PIAG 4-06(e)/2006	New Born Hearing Screening Wales (NBHSW) Evaluation
20/CAG/0157	The Oxford Risk Factors And Non-invasive imaging Study: ORFAN
18/CAG/0131	Inflammatory Bowel Disease Registry
23/CAG/0021	CSOR: Children's Surgery Outcome Reporting Research Database v1.0
CAG 9-08(b)/2014	Linkage of readmissions to birth data
18/CAG/0003	FAST- Febuxostat versus Allopurinol Streamlined Trial A prospective, randomised, open-label, blinded endpoint (PROBE) clinical trial evaluating long term cardiovascular safety of febuxostat in comparison with allopurinol in patients with chronic symptomatic hyperuricaemia
23/CAG/0015	Flatiron Health UK Oncology Research Database v2.0

Minutes ratified in correspondence from

Dr Tony Calland, MBE, CAG Chair, Professor William Bernal, & Dr Murat Soncul, CAG Alternate Vice-Chairs	*09 April 2024*
…….	……..
Signed – Chair	*Date*
Ms Caroline Watchurst, HRA Confidentiality Advisor	*05 April 2024*
…….	……..
Signed – Confidentiality Advice Team	*Date*