Health Research Authority

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

July 2023

1. New Applications

a. 23/CAG/0040 - Access to outcome data for patients treated by East Anglian Air Ambulance who are conveyed to the regional major trauma center (Cambridge University Hospitals NHS Foundation Trust)

Name	*Profession*
Dr Patrick Coyle	CAG Vice Chair
Dr Sandra Duggan	CAG Member
Dr Pauline Lyseight-Jones	CAG Member
Dr Harvey Marcovitch	CAG Member
Mrs Diana Robbins	CAG Member
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Purpose of application

This application from the East Anglian Air Ambulance set out the purpose of an audit and evaluation of the outcomes of the outcomes of patients treated by the service.

The East Anglian Air Ambulance (EAAA) provides pre-hospital critical care to patients across the East of England, in collaboration with the East of England Ambulance Service and attends around 1,600 critically ill and injured patients per year. EAAA do not routinely receive information about their patients after discharge from their care. Obtaining outcome data will allow EAAA to audit and evaluate the pre-hospital care they provide, with the aim of improving care for future patients of the air ambulance.

The most seriously injured patients in the East of England are conveyed to the single major trauma centre in Cambridge. The applicants seek support to allow the disclosure of confidential patient information from EAAA to Cambridge University Hospitals NHS Foundation Trust (CUHNFT). CUHNFT will then link patients treated by the Trust and EAAA between 2015 and 2022, and on a continuous monthly basis for two years from support being given. Confidential patient information will be disclosed from East Anglian Air Ambulance (EAAA) to CUHNFT. This will include patients NHS number and (if available) CUHNFT medical record number (MRN), in addition to a unique identifier. CUHNFT will match these patient identifiers to their electronic medical records. The second data flow from CUHNFT back to EAAA will contain anonymised outcome data that is uploaded directly to the EAAA patient record using the pseudonymised unique identifier.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients treated by East Anglian Air Ambulance and conveyed to the regional major trauma centre (CUHNFT) between 01/01/2015 - 31/12/2022., and on a

	continuous monthly basis for two years from the date support was given. The applicants estimate that 2983 patients will be included from 2015-2022. Based on historical trend data, the applicants anticipate the prospective monthly cohort would be approximately 35 patients per month.
Data sources	1. Electronic patient records at: a. East Anglian Air Ambulance b. Cambridge University Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. CUHNFT Medical Record Number (pseudonymised) 3. EAAA Unique Identifier (pseudonymised)
Identifiers required for analysis purposes	No identifiers are required for analysis

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Advise whether other methods of undertaking the audit, such as using data from the Trauma Audit and Research Network (TARN) database, had been explored. If this alternative had been determined not to be practicable, provide the rationale for this decision.**

The applicant explained that the Trauma Audit and Research Network (TARN) maintain a national trauma registry for the most seriously injured patients in England. East Anglian Air Ambulance (EAAA) work closely with TARN on research projects relating to this specific patient group, however in addition to major trauma a significant proportion of the incidents attended to by EAAA are medical emergencies, cardiac arrest, and ‘less severe’ injury. Incidents under these categories are not recorded by TARN and therefore would be excluded from the proposed audit and service

evaluation. The applicants also noted that TARN is limited to a standardised, predefined dataset and TARN also does not identify which patients were attended to by EAAA and therefore an anonymised dataset would not facilitate the detailed outcome data to satisfy the aims of the service evaluation and audit proposal.

The CAG noted this information and raised no further queries.

2. **Confirm whether support is needed for the return of the dataset from CUHNFT to EAAA. If support is not needed, further justification on why support is not required needs to be given.**

The applicants stated that support is requested to allow the disclosure of confidential patient information from East Anglian Air Ambulance to Cambridge University Hospitals NHS Foundation Trust (CUHNFT), and the return of a linked dataset from CUHNFT to EAAA.

The CAG noted this information and raised no further queries.

3. **Provide clarity on when the team will begin the prospective data collection.**

The Phase 1 (retrospective) data collection will take place from 01/01/2015 until support under s251 is confirmed. Phase 2 (prospective) will begin from the date confirmation of s251 support is received for a period of two years. The CAG noted this information and raised no further queries.

4. **Provide details on the type of work to be undertaken with the collected data.**

The applicants advised that work would be carried out to investigate air ambulance dispatch, diagnostic accuracy and intervention evaluation. Helicopter Emergency Medical Services (HEMS) are a scarce resource and optimising dispatch models to ensure the most appropriate patient group are treated is crucial to maintaining a sustainable service and improving patient outcomes. Outcome data, including hospital-delivered interventions, will allow EAAA to complete service evaluation work to better understand demand and identify areas where the dispatch process could be improved, and to consider the accuracy of conveyance or unnecessary conveyance of patients to the regional major trauma centre. The CAG noted this information and raised no further queries.

5. **Clarify whether patient NHS numbers, and EAAA and CUHNFT patient numbers, will be sufficient for linkage purposes, or whether additional identifiers, such as date of birth and postcodes, will be needed.**

The applicant advised that the NHS and EAAA/CUHNFT patient numbers will be sufficient for linkage purposes. No additional identifiers are required. The CAG noted this information and raised no further queries.

6. **Please ensure that a study specific patient notification and a specific dissent mechanism are created and displayed on the websites for EAAA and CUHNFT.**

Patients of EAAA or, if incapacitated, their next-of-kin, are routinely issued at-scene the details of the organisation with a QR code link to the EAAA website. This website outlines the EAAA privacy notice, which has now been updated to include study specific patient notification and dissent mechanisms.

Cambridge University Hospitals NHS Foundation Trust has agreed to update their published patient privacy notice to include study specific patient notification.

7. **Further patient and public involvement needed to be carried out, and this needed to include discussion of the use of confidential patient information as proposed in the application, and feedback provided.**

Further patient and public involvement was carried out at the East Anglian Air Ambulance Patient Forum Group on 16th May 2023. The meeting was attended to by 12 individuals and included representation from former patients, relatives of deceased patients, community fundraisers, dedicated aftercare nurses, and clinical representatives. The details of this specific application, including the processing of confidential patient information without consent between EAAA and CUHNFT, were discussed and examples of how patient's outcome data will be used were given, with reference to the work proposed. Support was overwhelmingly positive. The CAG noted this information and raised no further queries.

8. **Clarification on the exit strategy needs to be provided, including when the data will be anonymised, when the items of confidential patient information collected will be deleted, and where the pseudonymised key will be held and who will be able to access it.**

The pseudonymised key will only be available to the direct patient care team. All service evaluation and audit will be completed using a fully anonymised data set, without access to the pseudonymisation key or any confidential patient information. The CAG noted this information and raised no further queries.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. **Any future sharing of data outside the scope of section 251, such as, with other air ambulance trusts, must be returned to CAG for consideration, either via a new application or amendment.**

The applicants advised that their intention described in Section 2(m) of the CAG application form not to share outcome or patient data, but if this project is successful, to share the process of gaining approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') with other air ambulance services.

2. **A new application will be needed should the data collected be used for research purposes.**

The applicants agreed with this condition.

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **East Anglian Air Ambulance** & **Cambridge University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 11 April 2023)

b. 23/CAG/0073 - CompreHensive GeriAtRician led MEdication Review (CHARMER) - Work Package 4 Definitive Trial

Name	Capacity
Dr Martin Andrew	CAG member
Dr Sandra Duggan	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research that aims to test the effectiveness of the refined CHARMER intervention developed in the feasibility study, which is an intervention to support geriatricians and hospital pharmacists to proactively deprescribe for older people whilst they are in hospital, by measuring the impact proactive deprescribing has on readmission rates to hospital.

Research shows that almost half of older people in hospital are prescribed a medication with a risk of harm, but these medicines are rarely stopped. The reasons why geriatricians and hospital pharmacists do not proactively deprescribe for older people have been ascertained in a previous study. The research team has used this work to develop an intervention to support and encourage proactive deprescribing. This study has the potential to benefit patients in hospital by supporting clinicians caring for them to stop medicines that may cause harm. Stopping medicines should also reduce medicines administration burden and potentially improve medication adherence.

The deprescribing intervention developed and refined in earlier CHARMER studies will be compared to usual care on older people's medicine wards at twenty hospital sites in England. Twenty four hospitals will take part, in case hospital sites drop out during the study. Hospitals will begin as control sites and advance to receive the intervention at different stages in a stepped wedge design. Geriatricians and pharmacists at participating hospitals will receive the intervention, which will be tested for 4 weeks. All patients receiving care from clinicians on the study ward for the duration of the study will be enrolled. Routine data collection from site medical records will be collected for all patients. Consent will be taken where possible. ‘s251’ support will be required where consent is not possible. NHS number, Date of birth, and postcode, alongside a pseudo-ID will be disclosed to Norfolk and Norwich University Hospital NHS Foundation Trust, who will then disclose onwards to NHS England for the purposes of linkage to Hospital Episode Statistics (HES) (to identify readmissions), ONS data (to identify mortality) and prescribing datasets (to assess medication changes in primary care post discharge i.e. whether deprescribing was sustained). Most patient identifiers will be removed once data linkage is complete, however full date of death alongside other data is returned to Norwich Clinical Trials unit for analysis, therefore this flow also requires ‘s251’ support. This approach was tested in a recent feasibility study of CHARMER (22/CAG/0071).

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients under the care of a participating geriatrician on a study ward during the active study window who do not consent to the study. Total of 24,000 participants. Applicant estimates that a maximum of 3000 patients will provide consent to take part, therefore a minimum of 21,000 will require 's251' support
Data sources	1. 24 Participating NHS sites a) Medical records 2. NHS England: a) Hospital Episode Statistics b) ONS Mortality Data c) NHS Prescription Dataset
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Date of death

Confidentiality Advisory 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.

1. **Please provide the Favourable Opinion of the REC, as per standard condition of support.**

The applicant provided the Favourable Opinion from the REC, and the application can now be supported.

Confidentiality Advisory Group advice conclusion

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.

Specific conditions of support

The following sets out the specific conditions of support.

1. Please provide an update about the ongoing activities and further feedback from patient and public involvement, at annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 04 July 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. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England **21/22** DSPT reviews for **Norfolk and Norwich University Hospital NHS Foundation Trust, NHS England, & Norwich Clinical Trials Unit (EE133853-NMS-CTU)** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023)

   Due to the number of participating organisations involved it is the responsibility of University of Leicester, 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.

c.23/CAG/0019 - CLEOPATRAA Trial (Breast cancer molecular typing and grading trial)

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Dr Sandra Duggan	CAG Member
Professor Lorna Fraser	CAG Member
Mrs Diana Robbins	CAG Member
Mr Umar Sabat	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This application from Leeds Teaching Hospitals NHS Trust set out the purpose of medical research which aims to determine whether 4D Path's Technology Q-Plasia OncoReader Breast, that has been developed in the research setting, works robustly and reproducibly in the clinical diagnostic environment, to confirm its real-life clinical utility, in terms of breast carcinoma grading and molecular subtyping. Applicants will also establish the cost-effectiveness of the 4D Path platform. Applicants also wish to examine the long-term characteristics of the patient cohort, and the future potential applications of the technology.

Breast cancer is the most commonly diagnosed cancer worldwide, with approximately 55,900 new cases a year diagnosed in the UK. In order to determine the correct treatment for breast cancer patients, a biopsy is usually taken and reviewed by a pathologist, to obtain a definite diagnosis. The biopsy tumour tissue is also tested for oestrogen receptor (ER) and human epidermal growth factor receptor 2 (HER2) status – i.e. its 'molecular subtype'. The results from these tests inform oncologists in their choice of the most appropriate treatment for each patient. The results of these markers can also aid prognosis. These tests are usually interpreted by a pathologist. Carrying

out of these tests requires extra work from pathology laboratories as well as the extra reporting time/expertise from the pathologist. With only 3% of the UK's current pathology departments fully staffed to meet current demand, there is a need for a tool to help provide accurate and efficient reporting of breast cancer biopsies.

It is hoped that this tool could;

- improve earlier diagnosis of breast cancer, including molecular subtype results, to provide treatment-critical information to oncologists sooner,
- reduce cost to NHS laboratories by negating the need to perform additional tests when digital images of breast cancer biopsies can be used instead,
- eliminate the time a pathologist needs to spend interpreting these additional tests, freeing up time for more complex diagnostic work,
- freeing up laboratory staff who would otherwise be performing these extra tests, allowing allocation of their time to other critical tasks,
- avoid destruction of biopsy tissue which is otherwise needed to carry out these additional tests, leaving tissue for further potential research or testing,
- improve the diagnostic accuracy of grade on biopsy specimens (which is incorrect relative to the resection/excision specimen in about 20% of cases): this is clinically relevant in instances where patient receive neoadjuvant therapy.

The trial will run alongside the normal pathology workflow at St James's University Hospital (SJUH), (part of Leeds Teaching Hospitals NHS Trust), and make use of existing digitised pathology workflows, since slides for all cases that are reported by the department are digitally scanned for routine diagnostics. Eligible cases will be identified by the direct care team within the pathology laboratory system CoPath. At this stage, the National data Opt Out will be applied, by the Trusts Data Access Committee. 's251' support is required as the research team, who are not considered direct care team, will extract the digital images, clinical and pathological data required from the Trust digital pathology server, Sectra, and electronic patient records, which will require the research team to view confidential patient information. The research team are required to undertake these processes in order to keep the direct care team blinded. Digitised images of malignant breast cancer biopsies will be effectively anonymised prior to disclosing to 4D Path. Once the 4D Path algorithm has produced

a result, this will then be compared to the result produced by the reporting pathologist. The unblinding and comparison of the case diagnostic output comparison will be performed by the research team to avoid bias, which will also involve access to confidential patient information, and require 's251' support. The baseline clinical and pathological data will create a study database. This database will be retained by the direct care team only, so no 's251' support will be required for retention of the database. The database will contain LH number, (but no other identifying information), which the direct care team will use at 5 and 10 years to search the Trust clinical records for outcome data. Again, this will be outside the scope of 's251' support.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All patients with a breast biopsy specimen processed at the pathology laboratory at St James's University Hospital, Leeds Teaching Hospitals Trust approximately 700-800 patients over 12 months. This will start once all appropriate approvals are in place.
Data sources	1. Leeds Teaching Hospitals NHS Trust: a. Sectra imaging software - imaging b. LTHT laboratory information management system CoPath – specimen reports c. electronic health record (PPM+)
Identifiers required for purposes of creating a pseudonymised	1. NHS number 2. LH specimen number 3. Electronic patient record will be viewed

data set for analysis	
Identifiers required for analysis purposes	1. Age 2. Gender
Additional information	Follow up at 5 and 10 years will be undertaken by the direct care team only, and therefore no 's251' support required for this.

Confidentiality Advisory 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.

1. **The CAG requested an amended data flow diagram, which clearly outlines all the links and flows between data sources, clearly stating the common law legal basis for each flow so it is clear what 's251' support is requested.**

The applicant provided an amended data flow diagram, and CAG were content with this response.

2. **The patient notification materials need to be revised as follows:**

    a) **please ensure the wording and language of the patient notification documents is simple, and easy to read for a lay person.**

    b) **Please provide posters in clinical areas, including QR codes or links leading to further information on the website. Please ensure the opt-out options and contact details for local opt-out are clear.**

    c) **Please also add contact details next to information about local opt-out on the patient notification.**

    d) **Please change the wording where mentioned 'CAG Approval' as CAG is not the decision maker, it is more accurate to state that the**

application has been supported by the Health Research Authority (HRA) on advice from the Confidentiality Advisory Group (CAG).

e) **Please emphasise that the researchers will be looking at patient's documents and notes.**

The applicant initially provided updated materials, which the Sub-Committee were broadly content with. However some changes were requested, including that a phone number be added alongside the email address on the poster, correcting terminology surrounding complete anonymisation on the web notification, and additional reassurance that opting out will not affect care. The applicant made the suggested changes and CAG were now content.

3. **Please provide Favourable Opinion from the REC when it is available.**

This was provided by the applicant on 13 July 2023 as per standard condition of support.

Confidentiality Advisory Group advice conclusion

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.

Specific conditions of support

The following sets out the specific conditions of support.

1. Ongoing patient and public involvement needs to be undertaken specifically with breast cancer patients, to ensure public interest in the activity. Please also ensure that the wording of the online information and any other patient notification materials, such as posters, is reviewed by a relevant Patient and Public Involvement group, and feedback from this is to be provided to the CAG within 3 months from the date of this letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 13 July 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 **21/22** DSPT review for **Leeds Teaching Hospitals NHS Trust** was confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 03 February 2023)

d. 23/CAG/0051 - Retrospective analysis of real-world evidence on the use of glycopyrronium bromide in children under 3 years of age with sialorrhea

Name	Capacity
Mr Thomas Boby	CAG Member
Dr Ben Gibbison	CAG Member
Mr Anthony Kane	CAG Member
Ms Clare Sanderson	CAG Alternate Vice Chair
C. Marc Taylor	CAG Member
Professor James Teo	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Purpose of application

This research application from Alder Hey Children's NHS Foundation Trust and Proveca Ltd set out the purpose of medical research that seeks to Evaluate the safety and efficacy of using enteral Sialanar® (glycopyrronium bromide) to treat sialorrhoea (excessive drooling) in children under 3 years old, in terms of adverse events, suspected serious adverse events and the associated treatment discontinuation due to such events.

Sialanar® (glycopyrronium bromide) is currently licensed for the treatment of severe drooling in children and adolescents aged 3 years and older with chronic neurological disorders. The existing indication for Sialanar® was based on the position that salivary continence is not normally reached until 15–18 months of age in developmentally normal children. Consequently, drooling is not considered pathological below 3 years of age. Nevertheless, severe drooling is a significant issue for a proportion of children with chronic neurodevelopmental issues below 3 years of age, and it has become apparent that there is significant interest in and use of Sialanar® in children under 3, prescribed off label (use outside of the product license). This study will use retrospective patient data, of children under 3 who have been treated with this drug. It is hoped that a retrospective analysis of this age group, if shown to be an effective treatment, could evidence an expansion of the Sialanar® licence. This would give younger patients easier access to a product to help manage excessive drooling.

The study is limited to the review of existing medical records of participants from birth to 3 years of age treated with glycopyrronium bromide for sialorrhoea, at participating Trusts. ‘s251’ support is requested for the identification of potential participants, who will be identified through review of the available medical records at participating sites by research staff who are not considered direct care team. ‘s251’ support is also requested for the research staff to view medical records during the process of data extraction. Data will be collected for each individual participant for up to 36 months following the commencement of glycopyrronium bromide treatment, or to the age of 3 years whichever is less. ‘s251’ support is requested to allow date of birth and date of death to be uploaded to Redcap (hosted by University of Liverpool), alongside other clinical data, including sex, gestational age, body weight, length at birth, and medical history. Confidential patient information will then be removed by University of Liverpool, prior to analysis being undertaken on an effectively anonymous dataset by Alder Hey Children's NHS Foundation Trust. Any data onwardly disclosed to Proveca Ltd is effectively anonymised.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Participants from birth to 3 years of age treated with glycopyrronium bromide for sialorrhoea Planned sample size of approximately 50-100 patients. Data will go back up to 10 years, starting with the most recent available data.
Data sources	Medical notes from 5 Participating sites: • Alder Hey Children's NHS Foundation Trust • Gateshead Health NHS Foundation Trust • Nottingham University Hospitals NHS Trust • Guy's and St Thomas' NHS Foundation Trust • University Hospitals Bristol & Weston NHS Foundation Trust
Identifiers required for linkage purposes	1. Date of birth 2. Date of death 3. Sex Medical records will be reviewed to extract these data.
Identifiers required for analysis purposes	N/A analysis will be undertaken on a pseudonymised dataset.

Confidentiality Advisory 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.

1. **Please clarify how the research team identify which patients are eligible, and if ‘s251’ support is required for any screening of additional patients in the process.**

The applicant confirmed that the process would be slightly different at each site. Alder Hey Children's NHS Foundation Trust - potential patients for the study will be identified via extracts from the hospital dispensing system and hospital electronic records to identify patients taking glycopyrronium which will then be checked in accordance with Data Opt out process. No additional patients would need to be screened regarding this process. Gateshead Health NHS Foundation Trust - potential patients for the study will be identified via a patient list provided by direct clinical team and extracts from the hospital dispensing system, therefore no additional patients would need to be screened regarding this process. Nottingham University Hospitals NHS Trust - potential patients for the study will be identified via an extract from the hospital dispensing system, therefore no additional patients would need to be screened regarding this process. Guy's and St Thomas' NHS Foundation Trust – potential patients for the study will be identified via an existing patient database held by the PI at site, therefore no additional patients would need to be screened regarding this process. University Hospitals Bristol & Weston NHS Foundation Trust is yet to confirm their participation. The CAG were content with this response.

2. **Please provide an updated data flow diagram, in line with advice in this letter.**

The applicant has provided an updated data flow diagram, and the CAG were content with this response.

3. **Please confirm that any effectively anonymous data will be anonymised in line with ICO guidance, especially with regards to small numbers.**

The applicant has confirmed this and the CAG were content with this response.

4. **Please update the patient notification materials in line with advice in this letter and provide to CAG for review.**

The applicant provided an updated poster notification, which the CAG requested some changes to with regards to describing the process of pseudonymisation. Regarding the request for the generic medication name to be used in addition to the scientific name –

the generic name has been used on the poster already - ‘Glycopyrronium Bromide’ is the generic name, and unfortunately it’s not possible to state the brand name as the study is investigating more than one brand of Glycopyrronium. The applicant had emailed the new notification out to a group of parents for some patient and public involvement feedback, however only received one response. The CAG therefore requested the applicant undertake further patient and public involvement review of the poster before ‘s251’ support could be provided. The applicant provided further feedback from a relevant group of parents, and updated the documentation to align with this feedback. The CAG requested further changes to ensure the opt out options were clear, and also commented that they would expect to see ongoing patient and public involvement, and for the applicant to provide an update at annual review on any further discussions. The applicant provided updated documentation, clarifying how parents could opt their children out, and the CAG were content to support.

5. **Please provide clarity on an estimated time point for when the University of Liverpool would delete the date of death and date of birth from the electronic case report form (eCRF).**

Data will be deleted at the point of database lock, which is estimated as January 2024. The CAG were content with this response.

6. **Please justify why the key needs to be retained for 10 years.**

The key is required to be retained for audit purposes in line with Alder Hey Children's NHS Foundation Trust SOPs relating to research document retention. The CAG were content with this response.

7. **Please provide favourable opinion of the REC, as per standard condition of support below.**

This was provided 19 May 2023.

Response to condition

This letter also summarises a response to a condition set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Please reflect within the protocol that NHS numbers are no longer collected. Please submit this updated protocol within the next protocol amendment submission.**

The applicant confirmed that the study protocol has been updated to reflect the change that NHS number will be stored in the key at the site, but only by direct care team. NHS numbers are no longer uploaded to the electronic case report form (eCRF). The new version of study protocol Version 2.0 07.06.2023 will be submitted to REC as an amendment for approval. The CAG were content this condition was met.

Confidentiality Advisory Group advice conclusion

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.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 19 May 2023**

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. See section below titled ‘security assurance requirements’ for further information. **Confirmed:**

   Due to the number of organisations involved it is the responsibility of Alder Hey Children's NHS Foundation Trust and Proveca Ltd, as controllers, to ensure that participating Trusts meet the minimum required standard in complying with DSPT’s and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a Trust.

e. 23/CAG/0064 - Stroke Audit Machine Learning

Name	Capacity
Dr Patrick Coyle	CAG Vice Chair
Mrs Diana Robbins	CAG Member
Mr Umar Sabat	CAG Member
Ms Kathleen Cassidy	HRA - Confidentiality Advisor

Context

Purpose of application

This application from the University of Exeter College of Medicine and Health set out the purpose of medical research that seeks to investigate what a machine-learning model based on SSNAP data should look like and how it should be delivered.

Stroke is a leading cause of death and disability, with over 85,000 people hospitalised in the UK each year. One way of treating stroke and preventing disability is to treat with thrombolysis, where medication that breaks down blood clots is given. Thrombolysis is not suitable for all patients and can involve risk for some patients. For thrombolysis to be useful it needs to be given as soon after the stroke as possible. The use of thrombolysis varies hugely, even for patients with similar treatment pathways and with similar characteristics. Some hospitals rarely use it, some use it in a quarter of stroke patients. The speed of giving thrombolysis also varies. Some hospitals take an average of 90 minutes, others less than 40 minutes, to administer the drug. In a previous study, SAMUeL-1, reasons for variations in use of thrombolysis were investigated. One reason was clinical decision-making. The applicants are now seeking to collect further information on the clinical decision-making process.

The applicants will trace how physicians currently make decisions around stroke/thrombolysis in real time, and the resources and decision-making tools they have available. As part of this process of observation, the researcher will observe Multi-Disciplinary Team meetings during the sections where stroke care and thrombolysis are discussed. Observations of patient care will also take place. The researcher will overhear confidential patient information, but will not document, gather or process the information as it not relevant to the study. No confidential patient information will be used for research purposes.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	194 members of NHS staff will be included. Observations will be conducted in 3 hospital sites. It is not possible to give a precise figure for those included in the observations.
Data sources	1. Incidental disclosures of confidential patient information may be made during observations of staff meetings at: a. University Hospitals Sussex Foundation Trust b. The Royal Cornwall hospital Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be used for linkage.
Identifiers required for analysis purposes	No items of confidential patient information will be used for analysis purposes.

Confidentiality Advisory 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.

1. **The patient notification, specifically relating to the sections on data protection, to ensure that the wording flows appropriately and is not too complex, and the formatting is correct, and provide an updated document to CAG.**

A revised Patient Guide Sheet was provided. This was reviewed by the CAG, who raised no further queries.

Confidentiality Advisory Group advice conclusion

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.

Specific conditions of support

The following sets out the specific conditions of support.

1. Engagement with the Patient and Carer's Involvement Group is to be continued, including engagement with new volunteers, and ongoing patient and public involvement specifically related to this study. Feedback is to be provided at the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 25 July 2023**

3. Confirmation provided from the IG Delivery Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England **21/22** DSPT reviews for University Hospitals Sussex Foundation Trust & The Royal Cornwall Hospitals NHS Trust were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 31 May 2023)

   The applicant advised that the DSPT for Northern Lincolnshire and Goole NHS Foundation Trust is no longer required, as this Trust has been removed from the application.

2. New Amendments

18/CAG/0159 – Housing, family and environmental risk factors for hospital admissions in children

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to investigate the impact of environment and socio-economic factors on hospital admissions in children. The project uses an established birth cohort of infants born in England between 2005 and 2014. This is linked to 2011 Census Data and small area level data on air pollution and building characteristics in order to create a dataset to facilitate analysis. There have been many amendments to this initial 's251' support.

The applicant has 's251' support in place regarding children's dates of birth for the purposes of linkage, however not for the purposes of analysis.

This amendment seeks support for the applicant to access and use the full dates of birth and full dates of death of children in the cohort, in order to derive certain variables required for analysis, including follow up time and week and year of birth. Once these have been derived, applicants will downgrade all dates of birth for children in the birth cohort to week and year of birth. All these data are already held in the ONS SRS, and no further data transfers are required. Once the applicant has derived all variables, ONS will restrict access within the SRS to the date of birth and date of death variable on the birth registration data again.

Confidentiality Advisory Group advice
The amendment requested was considered by Chairs' Action. The Chair was content to recommend support for the amendment.

Confidentiality Advisory Group advice conclusion
In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 21/22 DSPT reviews for **the Office for National Statistics, University College London – School of Life and Medical Sciences & NHS England** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 20 June 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 30 June 2023**

21/CAG/0026 – High intensity treatment at the end of life in children with cancer: retrospective, national, data linkage study

Name	Capacity
Dr Murat Soncul	CAG Alternate Vice Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to determine whether the use of high intensity treatment at the end of life for children, teenagers and young adults with cancer, varies depending on the model of end of life care available. The application has 's251' support to allow the disclosure of confidential patient information from PICANET and ICNARC to NHS England (previously Public Health England (PHE)), for the purposes of linking to National Cancer and Registration System (NCRAS), ONS death certificate data, treatment information and hospital episode statistics datasets, and pseudonymising the data before transferring to the University of York (UoY).

The original application stated that a study specific opt-out would be advertised via PHE, the University of York, and the Children's Cancer and Leukaemia Group (CCLG) websites for 6 weeks prior to data extraction, directing the parents to contact PHE with any request to opt-out. The applicant also advised that existing opt-out notifications on the NCRAS, PICANet and ICNARC datasets will be respected, and the National Data opt out will also be respected.

This application was originally supported early in 2021. Due to COVID, the dissolution of PHE into NHS Digital, and subsequently into NHS England, there have been substantial delays to this application. This amendment sought support to remove the study specific opt out mechanism from this application, as NHS England have confirmed they do not have the capacity to apply any opt out to the NCRAS dataset. Existing opt-outs for the NCRAS, PICANet and ICNARC datasets will be respected, and the National Data opt out will also be respected.

The applicant reasons that the requirement for this amendment is not within the control of the research team, as this is a consequence of the restructuring and reorganisation of PHE and NHS Digital. If this amendment was not supported, then this study cannot be undertaken.

The applicant has confirmed the notification documents will be updated with regards to removing the opt out option.

Confidentiality Advisory Group advice

The amendment requested was initially considered by the Chair team. The Chair team initially recommended to run the study specific opt out through UoY, and for UoY to pass on opt out details to NHS England to uphold prior to data extraction from NCRAS. NHS England however have confirmed that they do not have capacity to do this. The

Alternate Vice Chair was therefore content that the applicant has exhausted all practicable alternatives, and it did not appear it was possible to operate a study specific opt out in this case.

The cohort are deceased, and usually this would mean that next of kin would be unable to opt out on behalf of a deceased participant, under common law, unless the next of kin was also the legal representative. This means CAG are often content that no notification or specific opt out is required when the entire cohort is deceased. In this application, even though the entire cohort are deceased, the parents will be legal guardians and would therefore be legally able to opt out under common law on behalf of their deceased children, which is why as part of the original application a study specific opt out mechanism was deemed appropriate. However, it was noted that 4 other types of opt outs were being respected, and the Alternate Vice-Chair was content to recommend support for this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 **21/22** DSPT reviews for **ICNARC, University of Leeds – LASER, NHS England, and the University of York (Department of Health Sciences)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 19 June 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 14 July 2023**

20/CAG/0157 – The Oxford Risk Factors And Non-invasive imaging Study: ORFAN

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to develop and validate novel imaging biomarkers to predict future heart attacks and other cardiovascular complications. Support is currently in place to allow the disclosure of confidential patient information from participating NHS Trusts to NHS England (previously NHS Digital), Arden & Gem CSU (on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR)), Kings College London (on behalf of the Sentinel Stroke National Audit Programme (SSNAP)), and local NHS Trust NIHR Biomedical Research Centres (BRC's) for the purposes of time limited linkage with clinical datasets, in order for anonymised linked datasets to be disclosed to the applicants at the University of Oxford.

This amendment seeks support to include The Newcastle upon Tyne Hospitals NHS Foundation Trust as a new participating site (new data processor for CAG).

The applicant has also provided an updated protocol which is accepted as notifications to CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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. See section below titled 'security assurance requirements' for further information. **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 07 June 2023**

21/CAG/0009 – Motor Neuron Disease Register for England, Wales and Northern Ireland (Research)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to create a research database that will act as a central resource of information about all people with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist in England, Wales and Northern Ireland, to enable the calculation of incidence and prevalence of MND in England, Wales and Northern Ireland. Confidential patient information will also be linked with clinical data

from national datasets. ‘s251’ support is in place to allow various collection of data, as detailed in the original outcome letter.

This amendment sought support to change the location of the data storage away from the use of SharePoint, as the applicants are changing to a secure server, also at King’s College London. As this is still part of Kings College London (KCL), there is therefore no change to the data processor, as this is covered by the KCL DSPT.

The amendment informed CAG of the collection of non-identifiable data, from submitting clinical sites. Since June 2015, (prior to ‘s251’ support), applicants collected non identifiable data about patients who were not consented, which did not require ‘s251’ support, as although pseudonymous, (to allow the submitting sites to re-identify), the applicants could not re-identify this data. Since ‘s251’ support has been in place, the applicant is now able to collect identifiable data since June 2015, including any patient who was not approached for consent. Only those who declined consent, or were invited to consent and did not respond cannot be included with identifiers. The applicant is seeking to receive effectively anonymous updates about those who declined consent, or were non responders, and as the described process does not breach confidentiality (ie. direct care team are the only individuals processing identifiable confidential patient information), this is not a change to ‘s251’ support, and is accepted as notification only.

The amendment also informed CAG that a palliative care trust, who is a data collection centre, confirmed that some of their patients are keen to take part, but some patients remain at home during their end of life care, and are unable to attend clinic. This centre wishes to provide the notification flyer to each patient, therefore they requested that an at home approach is added to the protocol, so these patients could be counted. This is accepted as notification only, as the applicants do not need to amend their ‘s251’ support for this, as the direct care team approaching patients for consent in their homes is not a breach of confidentiality and therefore no change to the ‘s251’ support.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, as most of these changes are accepted as notifications only, as they are not amendments to ‘s251’ support. These are noted in an outcome letter for clarity.

The CAT notes to the applicant that the palliative care Trust approaching patients for consent in their homes has 's251' support to include all those patients to the MND register anyway, without approaching for consent, under the 's251' support already in place. If the direct care team approach for consent, and the patient declines or does not respond, they can then not be included to the MND register. The register has 's251' to include identifiable information about these patients, without consent. Once consent is gained, (if at all), that is the individual patients exit strategy from 's251' support, however the patient is able to be included in the register either way, and these patients should not be required to consent to be included, as an alternative common law legal basis is in place, due to consent not being a practicable alternative as per outcome letter in April 2021.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 applicant, as controller, to ensure that all organisations processing confidential patient information 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. These will not be individually checked by the CAT team due to the number of organisations involved.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 23 March 2023**

21/CAG/0028 – Motor Neuron Disease Register for England, Wales and Northern Ireland (non research)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application aims to create a register that will act as a central resource of information about all people with a diagnosis of Motor Neuron Disease (MND) as confirmed by a consultant neurologist in England, Wales and Northern Ireland, to enable the calculation of incidence and prevalence of MND in England, Wales and Northern Ireland. Confidential patient information will also be linked with clinical data from national datasets. This non-research application is for the purpose of improving care planning, looking at regional differences, and enabling the applicants to provide answers associated with the NICE MND Audit. 's251' support is in place to allow various collection of data, as detailed in the original outcome letter.

This amendment sought support to change the location of the data storage away from the use of SharePoint, as the applicants are changing to a secure server, also at King's College London. As this is still part of Kings College London (KCL), there is therefore no change to the data processor, as this is covered by the KCL DSPT.

The amendment informed CAG of the collection of non-identifiable data, from submitting clinical sites. Since June 2015, (prior to 's251' support), applicants collected non identifiable data about patients who were not consented, which did not require 's251' support, as although pseudonymous, (to allow the submitting sites to re-identify), the applicants could not re-identify this data. Since 's251' support has been in place, the applicant is now able to collect identifiable data since June 2015, including any patient who was not approached for consent. Only those who declined consent, or were invited to consent and did not respond cannot be included with identifiers. The applicant is seeking to receive effectively anonymous updates about those who declined consent, or were non responders, and as the described process does not breach confidentiality (ie. direct care team are the only individuals processing identifiable confidential patient information), this is not a change to 's251' support, and is accepted as notification only.

The amendment also informed CAG that a palliative care trust, who is a data collection centre, confirmed that some of their patients are keen to take part, but some patients remain at home during their end of life care, and are unable to attend clinic. This centre wishes to provide the notification flyer to each patient, therefore they requested that an at home approach is added to the protocol, so these patients could be counted. This is accepted as notification only, as the applicants do not need to amend their 's251' support for this, as the direct care team approaching patients for consent in their homes is not a breach of confidentiality and therefore no change to the 's251' support.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, as most of these changes are accepted as notifications only as they are not amendments to 's251' support. These are noted in an outcome letter for clarity.

The CAT notes to the applicant that the palliative care Trust approaching patients for consent in their homes has 's251' support to include all those patients to the MND register anyway, without approaching for consent, under the 's251' support already in place. If the direct care team approach for consent, and the patient declines or does not respond, they can then not be included to the MND register. The register has 's251' support to include identifiable information about these patients, without consent. Once consent is gained, (if at all), that is the individual patients exit strategy from 's251' support, however the patient is able to be included in the register either way, and these patients should not be required to consent to be included, as an alternative common law legal basis is in place, due to consent not being a practicable alternative as per outcome letter in April 2021.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

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 applicant, as controller, to ensure that all organisations processing confidential patient information 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. These will not be individually checked by the CAT team due to the number of organisations involved.

21/CAG/0117 – CCP-Cancer UK: Clinical Characterisation Protocol for Severe Emerging Infections in the UK (CCP-UK) – a prospective companion study for patients with Cancer and COVID-19

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from University of Liverpool seeks to determine the Covid-19 fatality rate within the cancer population and to identify factors associated with poor outcomes from Covid-19 in patients with cancer. ‘s251’ support is currently in place to allow the disclosure of confidential patient information from the ISARIC CCP-UK study at the University of Oxford to the University of Edinburgh, and the onward disclosure of confidential patient information to the NCRAS dataset at Public Health England (now at NHS Digital) for data linkage, and the return of a pseudonymised dataset to the PHS Scottish National Safe Haven. ‘s251’ is also in place to allow confidential patient information from the ISARIC CCP-UK study to be disclosed from the University of Edinburgh to the University of Liverpool, where local research teams will access the REDCap database to populate the records of eligible patients. The University of Liverpool will then pseudonymise the data and send a pseudonymised dataset to the PHS Scottish National Safe Haven.

A previous amendment was supported in 2022, to allow disclosure of confidential patient information regarding approximately 500 Welsh patients to Digital Health and Care Wales via the Secure anonymised data linkage (SAIL) Databank, for their cancer data to be linked to their other healthcare data within SAIL and analysed to provide outcomes on the impact, treatment, plus future management of Welsh patients with cancer who also contracted COVID-19.

This current amendment sought support to remove the ‘s251’ support currently in place to disclose confidential patient information about 500 Welsh patients to SAIL for the purposes of linkage with Welsh outcome data. Due to the passage of time, the cancer data intended to be transferred to SAIL will have already arrived there via the normal dataflow processes used by DHCW. The data transfer is therefore no longer required or justified; to continue with it would be unnecessary. These data records will still be analysed as planned, it is just the route of the dataflow that has changed. Data collected by CCP-UK for Welsh patients will be analysed for the purposes of CCP-Cancer UK within the parameters of the SAIL databank.

This current amendment also sought support to remove the ‘s251’ support currently in place to obtain National Cancer Registration and Analysis Service (NCRAS) data from NHS England (previously NHS Digital), as applicants will no longer be requesting these data. NCRAS data would have been provided directly to the data safehaven at University of Edinburgh for linkage to and analysis with other data held for the CCP-UK study (the parent/companion study to CCP-Cancer UK) that would also have also been obtained from NHS England. The request for these NCRAS data is now being added to an amendment to the existing Data Access Request the parent study has in place, which is out of scope for this application. Due to delays the applicant has encountered in attempting to obtain these data, transferring the request to a different application will expedite the final analysis for this CCP-Cancer UK study, which is in the public interest.

The protocol has been updated to remove references to these now abandoned data transfers, and where required to their linkage and analyses. The contractual information has also been updated to the new arrangements. The updated patient information documentation is accepted as notification to CAG.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), who noted that this design was less disclosive than the original support.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 **21/22** DSPT reviews for **SAIL Databank and SeRP UK (within Swansea University), University of Edinburgh (SP186-EPCC), University of Oxford - Medical Sciences Division, and University of Liverpool** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 19 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 23 June 2023**

22/CAG/0038 – Twins' Early Development Study (TEDS) Medical Record Linkage

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application has ‘section 251 support’ to allow the disclosure of confidential patient information from the TEDS dataset, at KCL/SLaM CLDS Safe Haven to NHS England (previously NHS Digital), for linkage to the Personal Demographics Service, a second disclosure of confidential patient information to NHS England (previously NHS Digital) for linkage to the HES, MHSDS and IAPT datasets, and the return of a linked dataset, and also to allow the disclosure of confidential patient information from TEDS to participants’ GP surgery, for linkage to primary care electronic patient records, and the return of the linked dataset, for the purpose of creating a research database to investigate how genetic and environmental factors influence development, with a particular focus on psychological development and mental health.

This amendment sought support to include TEDS data into the UK Longitudinal Linkage Collaboration (LLC), CAG reference 21/CAG/0044. The current ‘section 251’ support for LLC allows;

- the disclosure of confidential patient information from UK longitudinal population studies (LPS) which currently operate under Regulation 5 support (named as NSHD, Sabre, TWINSUK, ALSPAC, with any additional studies requiring an amendment to LLC application) to NHS Digital Health & Care Wales (DHCW) (previously NHS Wales Informatics service (NWIS) as a trusted third party.
- for DHCW to onwardly disclose identifiers to NHS England (previously NHS Digital) for the purposes of flagging patients as LLC participants and linking with relevant English covid-19 related datasets, in order to supply the LLC database with pseudonymised linked data.
- and for DHCW to retain the identifiers relating to the LPS study cohorts to ensure de-duplication, and also to retain the key between the link ID and the key ID.

Therefore the support requested as part of this amendment includes the disclosure of confidential patient information in the TEDS dataset from South London and Maudsley NHS Foundation Trust, to NHS Digital Health & Care Wales (DHCW), for DHCW to onwardly disclose identifiers to NHS England for the purposes of flagging TEDS patients as LLC participants and linking with relevant English covid-19 related datasets, in order to supply the LLC database with pseudonymised linked data, and for DHCW to retain the identifiers relating to the TEDS cohort to ensure de-duplication, and to retain the key between the link ID and the key ID.

As per the LLC application, TEDS will deposit relevant de-identified study data from the TEDS research database into the University of Bristol’s Trusted Research Environment, and this flow does not require ‘s251 support’ as it does not contain any

items of confidential patient information, and LLC are unable to re-identify. However the flow is acknowledged, and this is a change in purpose to the TEDS application. Likewise, ongoing retention in the LLC database does not require support as it is held in pseudonymous format which LLC will not be able to re-identify, and therefore University of Bristol - Longitudinal Linkage Collaboration is not an additional processor for the TEDS 's251' application, and a DSPT is not required.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to recommend support for this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 **South London and Maudsley NHS Foundation Trust (RV5), and NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 18 July 2023)

   Regarding participating GP surgeries; due to the number of organisations involved it is the responsibility of King's College London, as controller, to ensure that participating 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.

Security assurances for NHS Digital Health & Care Wales (DHCW) is confirmed by the Welsh IG team.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 26 May 2023**

ECC 3-04(i)/2011– Global surveillance of cancer survival (CONCORD programme)

Name	Capacity
Dr Tony Calland, MBE	CAG Chair
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the London School of Hygiene and Tropical Medicine set out details of the UK arm of a global surveillance of cancer survival systematic comparison of international differences and trends in cancer survival. Data is collected from England, Wales, Scotland, and Northern Ireland, however the Scottish and Northern Irish flows of data are outside the scope of this 'section 251' support.

For England, individual patient data is provided by NHS England, from the National Cancer registration and analysis service (NCRAS). This dataset will include full dates of birth, diagnosis and details of death, as the NCRAS dataset already contains linked ONS mortality data.

For Wales, individual patient data is provided by the Welsh Cancer Intelligence and Surveillance Unit, (part of Public Health Wales), which holds the cancer registry for Wales. This dataset will again include full dates of birth, diagnosis and fact and date

of death, as the Welsh dataset already contains linked mortality data.

A CAG amendment supported in March 2017 covered an extension of the programme from 2009 to 2014 (entitled CONCORD-3), and the addition of data for five more common malignancies - oesophagus, pancreas, melanoma of the skin, lymphomas and brain tumours, to total 15 types in adults, and 3 types in children. The duration of retention of the CONCORD-2 data (from 1995-2009), was extended until 31 December 2020, for ongoing analyses and publications.

The current amendment sought support to extend the duration of the data retention of the identifiable data from CONCORD-3 (2000-2014), CONCORD-2 (1995-2009), and CONCORD-1 (1990-1994), until 31 December 2027, for ongoing analyses. The data for CONCORD-1 study, published in 2008, are no longer used, however applicants would prefer to retain them to enable rapid re-checking of the frequencies of diagnosis of incident cases by age, sex, cancer site and year of diagnosis in the unique data sets that were used in the estimation of survival. However, 15 years after publication, the dataset is already archived, but the applicant has suggested that dates of birth could be removed, thus rendering the data anonymised. The applicant also seeks support to retain identifiable data collected as part of CONCORD-4 until 31 December 2027.

The current amendment also sought support for the 4th cycle of data collection, CONCORD-4, to include patients diagnosed during the 20-year period 2000-2019. However, some of the oldest international cancer registries will also provide earlier data, for patients diagnosed during 1990-1999, to enable examination of very long-term survival trends. Some of the most up-to-date registries will also be able to include data for patients diagnosed during 2020-2021. With regards to England and Wales, it is therefore possible that submissions from England and Wales will span from 1990-2021.

This amendment also sought support for coverage to extend to include 22 cancers in adults, extended from 15. The additional 7 adult cancers are those of the lip and oral cavity, larynx, thyroid, gallbladder, corpus uteri, kidney and urinary bladder. CONCORD-4 will also include **all** childhood cancers. Applicants analysed survival from brain tumours, leukaemias and lymphomas in children in CONCORD-3, and are expanding CONCORD-4.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair agreed with the suggestion of the applicant with regards to anonymising the CONCORD-1 data by deleting the date of birth from the archived dataset. Therefore CONCORD-1 will no longer require 's251' support for retention. The Chair was content to recommend support for the new iteration of data collection – CONCORD-4, and for the duration extension for retention of identifiable data collected as part of CONCORD-2 and CONCORD-3 until 2027. The Chair stated that any further extension to the duration of retention will require another amendment with full justification.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. The data retention of confidential patient information already collected in CONCORD-1 (1990-1994), will exit from 'section 251' support as the applicant will delete the date of birth and render the dataset anonymous.

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 21/22 DSPT review for **Cancer Survival Group-London School of Hygiene & Tropical Medicine** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 18 July 2023)

   The NHS England 22/23 DSPT review for **NHS England** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 18 July 2023)

Welsh IG team have confirmed security assurances are in place for **Public Health Wales (which covers the Welsh Cancer Intelligence and Surveillance Unit)**

3. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 10 May 2023

CR17/2014 – EPIDEMIOLOGICAL STUDY OF BRCA1 AND BRCA2 MUTATION CARRIERS

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Cambridge has support in place to access mortality and cancer data from NHS England, to follow-up a cohort of BRCA1 and BRCA2 mutation carriers with associated epidemiological, clinical, pathological and genetic data to study cancer epidemiology in mutation carriers.

This amendment is to confirm that Professor Doug Easton is retiring, and the new Chief Investigator is now Professor Antonis Antoniou.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 21/22 DSPT review for **University of Cambridge (School of Clinical Medicine) &**

   The NHS England 22/23 DSPT review for **NHS England** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 12 December 2022**

22/CAG/0009 - Early detection of bladder cancer in Yorkshire: Feasibility assessments for implementing a targeted study in populations with high disease specific mortality risk

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from participating GP practices to iPlato Healthcare, for Cohort 2, and to

the Participating NHS Trust Research Team, for Cohort 3, and to King's College London for both Cohorts, and then to Testcard Ltd, who will undertake the mailout to selected participants, and support to disclose confidential patient information to NHS England for linkage to NCRAS for follow-up data.

This amendment sought support to extend the duration of 's251' support until 30 June 2024. The cause of this extension is due to the 12 month recruitment period commencing later than anticipated (3rd October 2022). Applicants currently anticipate that recruitment into the study will end on 30th September 2023 (last invitation dispatched). This extension will enable applicants to recruit for the 12-month period as described in the initial application. The end of trial definition is anticipated to be met by 30th March 2024, however support is extended longer than that in case these timelines are not met.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 **21/22** DSPT reviews for **Testcard Ltd, iPlato, King's College London Cancer Epidemiology and Population Health (CPTU), &**

The NHS England **22/23** DSPT review for **NHS England (NCRAS)** were confirmed as '**Standards Met'** on the NHS England DSPT Tracker (checked 21 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 19 June 2023

22/CAG/0090 – ISIS 2 Second International Study of Infarct Survival: Legacy Database

Name	Capacity
Ms Kathleen Cassidy	Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the University of Oxford to continue to hold confidential patient information collected for the ISIS-2 study. When the CAG recommended support, a condition was placed that the dataset could be retained in an identifiable format for 12 months following issue of the outcome letter. After 12 months, the dataset was to be anonymised and all items of confidential patient information deleted.

In the amendment, the applicants seek support to extend the duration of support to allow for holding of the identifiable dataset for a further 6 months. The applicants plan to undertake linkage of the ISIS-2 dataset to the GP Data for Planning and Research (GPDPR). GPDPR has not yet been launched, but the applicants anticipate it will be launched in the next year.

Noting that the CAG did not want the identifiable dataset to be held for an extended period at the University of Oxford and, following a suggestion from the CAG, the applicants plan to pseudonymise the datasets held at the University of Oxford and use a Trusted Third Party to hold the trial linkage identifiers until the linkage to the GPDPR data can be done. The Trusted Third Party has not yet been identified. An amendment will be submitted to seek support for the transfer of confidential patient information to the Trusted Third Party at a later date.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team who agreed that the amendment was in the public interest.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. The dataset is to be retained in an identifiable format until 04 January 2024. After this date, the dataset is to be anonymised and all items of confidential patient information deleted.

2. Favourable opinion from a Research Ethics Committee. **Confirmation provided that an amendment to REC is not required.**

3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS Digital **2020/21** DSPT review for **University of Oxford (Nuffield Department of Population Health)** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 27 June 2022)

21/CAG/0104 – Enhancing Pre-hospital Chest Pain Telephone-triage Using a Prediction Model

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application seeks to investigate whether the use of a prediction model in telephone triage can reduce the over-triage of chest pain patients. ‘s251’ support is in place to allow the disclosure of confidential patient information from North West Ambulance Services NHS Trust to the University of Manchester, then onward disclosure to the University of Manchester NHS Foundation Trust for linkage to data held by the Trust and the return of a linked dataset to the University of Manchester.

This amendment sought to extend the duration of ‘s251’ support until 30 January 2024.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 21/22 DSPT reviews for **University of Manchester, Manchester University NHS Foundation Trust & North West Ambulance Services NHS Trust** were confirmed as ‘Standards Met’ on the NHS England DSPT Tracker (checked 24 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 24 June 2023

21/CAG/0017 – Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales: a retrospective cohort study: OPTIC-19

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the Intensive Care National Audit and Research Centre (ICNARC) to NHS England (previously NHS Digital), Digital Health and Care Wales, NICOR, SSNAP and the UKRR, for the purposes of time limited linkage with clinical datasets in order for pseudonymised linked datasets to be disclosed to the applicants at the University of Oxford, and for the return of full date of death from NHS England and DHCW to the University of Oxford.

This amendment sought support for an increase of the initial cohort size to include participants admitted to ICU from January 2016 to 30 June 2022. ‘s251’ support is currently in place to include participants admitted to ICU from January 2016 to July 2020.

The amendment also sought to extend the duration of ‘s251’ support until 31 August 2024.

Applicants will also additionally collect COVID-19 vaccination status as a data item, and include selected causes of death (major adverse cardiac event, respiratory infection, venous thrombotic event) as secondary outcome measures. However these additions do not alter the ‘s251’ support in place, as there is no change regarding items of confidential patient information processed under ‘s251’ support. CAG accept these changes as notifications.

The patient notification document has been updated to reflect the relevant changes, and these are accepted as notification.

This amendment will enable applicants to expand analysis by exploring whether outcome rates were affected by changes in treatment pathways, the dominance of particular SARS-CoV-2 variants and vaccination rates over time. Including death by specific causes will allow applicant to determine the primary cause of death for participants who died in the community.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed: Due to the number of organisations involved it is the responsibility of University of Oxford, 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. **Changes to data items and cohort size - Confirmed 10 July 2023, & duration extension confirmed as non substantial 5 July 2023**

22/CAG/0125 – Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency: Link MAP-CLD

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The overall aim of this study is to identify which characteristics of treatments and services for acutely ill people with CLD impact on care processes and outcomes, in order to improve the national organisation and delivery of care for all people acutely ill with chronic liver disease. The application has 's251' support to link together data from NHS England (previously NHS Digital), Intensive Care National Audit & Research Centre (ICNARC), and NHS Blood and Transplant (NHSBT) about 100,000 patients with Chronic Liver Disease (CLD). NHS England will identify the eligible cohort using Hospital Episode Statistics and ONS Mortality Datasets.

'section 251' support is currently in place regarding '*all patients older than 18 years (or with missing age) with chronic liver disease (CLD) who were admitted with a first emergency hospital admission between 1 April 2009 and 31 March 2022'.*

This amendment sought support to clarify that the cohort should be described as; '*All patients older than 18 years (or with missing age) with chronic liver disease (CLD) who were admitted with an emergency hospital admission between 1 April 2007 and 31 March 2022'.* This new description removes the word "first", and changes the dates from between '*1 April 2009 and 31 March 2022'* to '*1 April 2007 and 31 March 2022'*

The purpose of this change is to allow LSHTM (data processor) to receive all emergency admission records, and apply the first admission filter, rather than NHS England filter by first admission, as this will more reliably identify first emergency admissions.

As part of this amendment, the applicant provided an updated privacy notice, which has been accepted as notification only. The previous privacy notice referred to approval from the Independent Group Advising on the Release of Data (IGARD). NHS

England have identified that IGARD do not approve data sharing agreements, only advise on them, with NHS England providing the approval. Applicants have therefore updated the wording of the privacy notice to reflect this. The previous version was also missing reference to the UK GDPR legal bases for processing, the rights available to individuals in respect of the processing and the right to lodge a complaint with a supervisory authority. Applicants have also corrected these omissions in the latest privacy notice.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

The following sets out the specific conditions of support.

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 21/22 DSPT reviews for **Intensive Care National Audit & Research Centre, NHS Blood and Transplant, NHS England & London School of Hygiene and Tropical Medicine** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 26 July 2023)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 24 July 2023**

3. Annual Review Approvals

CAG reference	Application Title
21/CAG/0160	Secondary/additional findings in the 100,000 Genomes Project: disease manifestation, impacts on recipients and healthcare utilisation
16/CAG/0071	Benchmarking Clinical Quality Healthcare Measures
21/CAG/0144	Risk of Covid-19 related hospital admission and death in cancer patients in Greater Manchester
14/CAG/1006	Millennium Cohort Study (MCS)
17/CAG/0126	Surveillance of Severe Microcephaly in the UK and Ireland(SSM-UKI)
18/CAG/0024	Pregnancy Outcome Prediction Study: Transgenerational and Adult Review (POPStar)
22/CAG/0070	Implementation of an artificial intelligence module on the online imaging portal MYO-Share for guiding the diagnosis of muscle diseases.
CR12/2014	Oxford Vegetarian Study also known as Study of Cancer in Vegetarians
20/CAG/0104	POST-BOX: Consensus-building a post-partum haemorrhage kit using citizen science (Workpackage 1)
19/CAG/0012	Long term outcomes in Hirschsprung's and anorectal malformations
21/CAG/0104	Enhancing Pre-hospital Chest Pain Telephone-triage Using a Prediction Model
18/CAG/0064	National Bone and Joint Infection Registry
22/CAG/0019	CUREd+ Research Database
21/CAG/0117	CCP-Cancer UK: Clinical Characterisation Protocol for Severe Emerging Infections in the UK (CCP-UK) – a prospective companion study for patients with Cancer and COVID-19

22/CAG/0075	Clinical and Radiographic outcomes of reverse shoulder arthroplasty performed with 36-mm CoCrMo vs 40-mm cross-linked UHMWPE glenospheres at minimum 2-years follow-up.
PIAG 2-10(g)/2005	National Gestational Age Statistics: Linkage, Analysis and Dissemination of National Birth and Maternity Data for England and Wales
ECC 3-04(i)/2011	Global surveillance of cancer survival (CONCORD programme)
18/CAG/0159	Housing, family and environmental risk factors for hospital admissions in children
20/CAG/0027	Congenital Heart Audit: Measuring Progress In Outcomes Nationally (CHAMPION)
17/CAG/0150	National Perinatal Mortality Review Tool (PMRT)
16/CAG/0066	Hospital Alerting Via Electronic Noticeboard (HAVEN)
17/CAG/0096	SEARCH: A population based study of genetic predisposition to breast cancer
17/CAG/0098	SEARCH: A population based study of genetic predisposition to endometrial cancer
17/CAG/0097	SEARCH: A population based study of genetic predisposition to ovarian cancer
18/CAG/0066	United Kingdom Childhood Cancer Study
22/CAG/0100	National Cancer Patient Experience Survey 2022-2024
ECC 3-04 (f)/2011	Information Governance Clinical Dataset Linking Service
16/CAG/0063	aTTom Extended – Extended follow up of patients enrolled in the Adjuvant Tamoxifen Treatment – Offer More? (aTTom) trial
20/CAG/0049	PREDICT Study: RaDaR and UKRR Linked Dataset
22/CAG/0073	Kidney disease and mental health: Bridging the gap
ECC 1-03(FT2)/2010	Prospective Study of Outcomes in Sporadic versus Hereditary breast cancer (POSH)

Signed – Chair	Date
Dr Tony Calland, MBE, CAG Chair, Dr Patrick Coyle, CAG Vice-Chair, Dr Murat Soncul, & Ms Clare Sanderson CAG Alternate Vice-Chairs	*11 August 2023*

Signed – Confidentiality Advice Team	Date
Ms Caroline Watchurst, HRA Confidentiality Advisor	*01 August 2023*